

Exhibit 18

*State of California ex. rel. Ven-A-Care of the Florida Keys, Inc. v.
Abbott Laboratories, Inc., et al.*

Exhibit to the Declaration of Nicholas N. Paul in Support of
Plaintiffs' Opposition to Defendants' Joint Motion for Partial Summary Judgment

June 30, 2009

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESAL PRICE LITIGATION)	
)	
)	MDL No. 1456
)	Civil Action No. 01-12257-PBS
)	
THIS DOCUMENT RELATES TO:)	(Original Central District of California No. 03-CV-2238)
)	
<i>State of California, ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.</i>)	Hon. Patti B. Saris
)	

Expert Report of Professor Theodore R. Marmor, PhD**I. Assignment**

I have been asked to offer my opinions about the following questions posed by plaintiffs, the State of California and Ven-A-Care, in this action:

1. Does the historical record of Federal and California governmental policy on Medicaid drug reimbursement support the proposition that the relevant organizations of the California government (including, but not limited to, the Department of Health Care Services and the Legislature) approved of or acquiesced in Dey's, Mylan's and Sandoz's price-reporting conduct as alleged in California's Amended Complaint?
2. Explain whether and if so, how, my experience, training, and education in the fields of political science and public policy enable me to apply accepted and reliable principles or methods in my field to answer the above question. Describe those accepted and reliable principles and methods.
3. How do the following facts and information bear on my opinions about question 1?
 - (i) Medi-Cal's continued use of published prices (AWPs, Direct Prices);
 - (ii) The record of Ven-A-Care's (VAC) communications with various persons within the Federal Government (Congress, HHS, HCFA) and California;
 - (iii) Federal and State reports including those issued by the Office of the Inspector General (OIG), the California State Controller and studies by and for the California Medi-Cal program; and

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- (iv) Federal and California (legal) investigations of drug pricing and reimbursement.

II. Executive Summary of Opinions as To the Three Questions Posed

Question 1: *Does the historical record of Federal and California governmental policy on Medicaid drug reimbursement support the proposition that the relevant organizations of the California government (including, but not limited to, the Department of Health Care Services and the Legislature) approved of or acquiesced in Dey's, Mylan's and Sandoz's price-reporting conduct as alleged in California's Amended Complaint?*

Answer:

In my opinion the historical record does not support the proposition that the Federal or California governments approved of or acquiesced in the alleged conduct by the three defendants. This proposition does not directly address whether Government officials---at the federal or state level---were aware of claims that drug firms were charging their customers less than the drug firms reported. Rather, the key question is whether the price-reporting conduct (specifically the alleged fraudulent conduct of the defendants) that is set out in the complaint was a) known in detail to the public officials and b) approved of or acquiesced in by the State of California.

At a later point in this report, I will address the significance of investigative reports that provided snapshots of particular drug prices in California. My opinion here rests on premises that are, to my knowledge, unchallenged. First, to approve of conduct (or acquiesce in its continuation), one must know what that conduct was, with a level of detail that depends on the nature of the policy asserted. Second, the historical record needs to reflect an informed consideration of the conduct, followed by a formal and (normally) public iteration of the government policy. This is all the more so when the "policy" that is claimed to have existed conflicts with clear, consistent statutes or regulations during the relevant time period. Even government acquiescence, if considered the relevant standard of government conduct, requires an affirmative showing of formality and documentation that distinguishes government acquiescence from simple inattentiveness, lack of political will or consensus about a remedy, or even spotty implementation of policy by careless or overworked employees.

Finally, particularly if the historical record and written documentation of formal policy are not unequivocally clear, one must examine collateral historical evidence to know whether there were developments that contradict what is asserted to be the government policy or whether there are stated policies, governing statutes or regulations that are contrary to the asserted government policy. In addition, there is the question of whether a mere course of conduct or absence of affirmative response to information is sufficient to rise to the level of government policy where a claimed policy was not stated as one would have expected it to have been.

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Here, the officials whose record I have reviewed did not know in detail the conduct alleged in the California complaint, at least until the law suit was filed (and certainly the law suit contradicts any claim of acquiescence). Therefore, until that date it would be logically impossible to have approved of or acquiesced in the conduct alleged. The record does show various examples of reports and investigations that studied drug pricing. Moreover, there were examples of conclusions reached about average price differentials between invoice prices and prices reported to various compendia. But there has been no showing of ongoing, detailed information known to the pertinent California officials about specific drugs. Nor was there information available to California officials to document deliberate manipulation of reported drug prices by these defendants for commercial purposes.

Second, I am aware of no formal statement of policy by a California or federal official that approved of the price reporting conduct identified in the State's complaint by these defendants. To the contrary, the record abundantly shows that Medi-Cal, in accordance with federal and State mandates, sought to estimate provider acquisition costs in its drug reimbursement program.

Further, the record provides no evidence that the defendants communicated their pricing conduct, much less obtained governmental approval of that conduct. Instead, they provide documentary evidence that one or another specific fact about drug spreads was known to one or another governmental official. But it does not follow that such knowledge established approval of the facts alleged. There is a fundamental reason for this – one that is often overlooked. The claims in this suit are about particular firms, particular prices, and particular spreads. On the other hand, the knowledge cited in the depositions of California officials had almost entirely to do with findings of average spreads by the federal Office of the Inspector General. The difference between those average findings and the findings required to reimburse accurately for particular drugs is an additional counter-argument to the claims of approval or acquiescence. Finally, pharmaceutical companies, including the defendants, went to significant lengths to thwart change as well as discovery of their pricing conduct – including a lawsuit against First DataBank when it started reporting much lower (and more accurate) AWP's than one of the defendants wanted it to report.

Question 2: Explain whether and if so, how, my experience, training, and education in the fields of political science and public policy enable me to apply accepted and reliable principles or methods in my field to answer the above question. Describe those accepted and reliable principles and methods.

Answer:

This report consists of two parts: one, my historical account of drug reimbursement policy at the federal level (both Medicaid and Medicare) and, two, the outline of the reliable analytic methods I bring to questions of how public policies arise and evolve over time. I have applied that analytical approach to the California experience during the period 1994-2004. My qualifications as well as this approach are described in detail below.

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Question 3: *How do the following facts and information bear on my opinions about Question 1?*

- (i) *Medi-Cal's continued use of published prices (AWPs, Direct Prices);*
- (ii) *The record of Ven-A-Care's (VAC) communications with various persons within the Federal Government (Congress, HHS, HCFA) and California;*
- (iii) *Federal and California reports including those issued by the Office of the Inspector General (OIG), The California State Controller and studies by and for the California Medi-Cal program; and*
- (iv) *Federal and California (legal) investigations of drug pricing and reimbursement.*

Answer:

(i) Medi-Cal's continued use of published prices (AWPs, Direct Prices). There is no factual dispute about the continuing use of average wholesale and direct prices in California's reimbursement of drugs over the decade this suit covers. But over this period there is a solid record of successful efforts to constrain the costs associated with either of the two methods. During most of the period, direct prices were typically lower than the AWPs reported in the price compendia. To the extent that advantaged California fiscally, there is no problem to cite. First, California applied 5% discounting from AWP. Second, there was the 10% rebate program between 1994 and 1996, itself an important contributor to lower net costs of Medi-Cal's drug program. This rebate program, however, was not directed at the conduct alleged in this complaint. Third, there was the 1995 (effective) across-the-board reduction by fifty cents of each prescription, a reduction that itself was reduced over time. The shift from AWP minus 5% to AWP minus 10% in 2002 illustrates the response of California's policy makers, with a lag, to additional inflationary developments in the pharmaceutical industry. And, finally, following the report of the accounting firm Myers & Stauffer, California adopted an AWP minus 17% standard in 2004.

These facts leave out the many discussions (and policy developments) within California's governmental organizations of what else could have been attempted to deal with the rising costs of providing drug coverage to Medi-Cal's patients. But, in line with accepted political science understandings, a major change in a fiscally significant area of public policy does not typically take place until three conditions are met: there is wide agreement on the type and scale of the problem; there is a remedy available that those who have the authority to authorize a change in policy believe is appropriate; and, finally, that the appropriate policy option is operationally feasible. That is, the policy can be implemented by the available organizations. So, the distinction that is important here is between adjusting policy (by discounting) and changing policy. The former is more common than the latter in public policy and thus helps to explain California's pattern of conduct described in the above paragraph.

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(ii) The record of Ven-A-Care's ("VAC") communications with various persons within the Federal Government (Congress, HHS, HCFA) and California. This report describes what VAC did as a "campaign" to alert federal officials as well as state officials to what they regarded as unknown, but outrageous spreads in the prices of the drugs listed, most importantly, by First DataBank. The story shifts to California in 1998, when VAC presented its contentions to California officials, especially those connected with fraud investigations. The depositions of California Health Department officials show that VAC also checked its claims of extraordinary inflation in the drug prices reported to California's fiscal intermediaries. (*See, e.g., Hillborn and Rosenstein depositions*).

VAC's contribution to the California litigation, it appears, was to persuade officials that the magnitude of the spreads was much greater than what most investigators had previously imagined. VAC also claimed that the practice of reporting inflated drug prices was a deliberate effort by drug manufacturers to create economic incentives for their customers to buy their products. In that sense, VAC's revelations followed on OIG investigations of price differentials. They did so by providing background information about the motives and opportunities of various sectors of the pharmaceutical industry. VAC also buttressed its argument with more detailed information on particular drugs, both their reported and their actual prices. VAC filed its California lawsuit in 1998, but it was under seal until 2003 when California's Attorney General intervened on behalf of the state. In that five year period, there were numerous investigations, continued efforts by VAC to enlist California, and understandable and extensive research before California's legal officials agreed to join the suit. They did so initially in connection with two defendants, Abbott and Wyeth, but later joined the suits against a much larger number of defendants. In short, VAC's efforts were a prod to legal action by other parties, an instance of another governmental channel of action to redress what was increasingly asserted to be fraudulent conduct. In no way do VAC's actions challenge my opinions that neither federal nor California officials approved or acquiesced in the price reporting conduct of the defendants. Instead, their actions inform my understanding of how this public policy development took place.

(iii) Federal and California reports, including those issued by the Office of the Inspector General ("OIG"), the California State Controller, and studies by and for the California Medi-Cal program. These reports play three roles in my analysis. I regard the OIG reports as problem identifiers -- but without sufficient specificity and representativeness to offer a remedy to either the federal or state programs. In conjunction with VAC's efforts to expose the manipulations by various drug manufacturers, OIG played a large role in bringing allegations of misrepresented drug prices to the public agenda, particularly in Washington, DC. The California State Controller played a somewhat similar problem-identifier role, but as part of the internal California governmental disputes about how much and how fast to increase discounting from AWP reported prices. Studies done for the California Medi-Cal program--such as the Myers & Stauffer investigations of 2002-04--were directed at more specific questions about how adequate and accurate the current dispensing fees and ingredient cost reimbursements were in light of all the allegations of substantial overpayment. If the

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OIG reports suffered from using averages and limited samples of drugs, the Myers & Stauffer study was more central to prompting legislative action. The study was in part a result of an appellate court's (9th Circuit) earlier refusal to permit an across the board decrease in payments because there was no detailed research to back up the figures at issue in that case. This was part of the background to both the 2002 and 2004 legislative changes in California.

More generally, none of these reports challenge my answer to question 1. Quite the contrary, they reveal an increasing incremental understanding of the extent of the problem of drug price inflation, and, over time, accumulation of the detail needed to enlist California's legal authorities to take on the problem via litigation. The California Department of Health was the responsible program unit, just as HCFA (and then CMS, the Center for Medicare & Medicaid Services) was the operational program administrator for Medicare and federal oversight to Medicaid. In both cases, the program operators left litigation – *i.e.*, the decision about whether and when to escalate to that level -- to the institutional units responsible for that channel of action: the Federal Department of Justice and the California Attorney General and its fraud division.

(iv) Federal and California (legal) investigations of drug pricing and reimbursement. This is incorporated in my answer to (iii), above.

III. Qualifications

4. The attached curriculum vitae provides a detailed description of my educational, professional and scholarly background. Here, I will highlight only those aspects most relevant to my analysis of issues in this case.

5. I was educated at Harvard College and University and took my doctoral degree in American politics and history in 1966. My formal education includes a fellowship year at Wadham College, Oxford (in philosophy, politics and economics) and a post-doctoral fellowship at the Harvard School of Public Health in 1966.

6. I recently retired as Professor of Public Policy, Political Science and Management at Yale University, where I have taught since 1979. I have also been an adjunct professor at Yale Law School, where I have taught the course on health politics,

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policy, and law since 2002. My prior academic positions were at the Universities of Wisconsin, Minnesota, and Chicago.

7. My scholarship has concentrated on the study of public policy (both domestic and comparative), emphasizing over the past two decades disputed issues in health and health care. My book, The Politics of Medicare, has been continuously in print since 1970, with an expanded, second edition in 2000. I was the co-author, with Yale colleagues, of a book published in 1990 on America's Misunderstood Welfare State: Persistent Myths, Continuing Realities. Most recently, I published a set of essays entitled Fads, Fallacies and Foolishness in Medical Care Management and Policy (2007). For the period 1987-95, I was a fellow of the Canadian Institute for Advanced Research and, with others, edited and contributed to a book on Why Some People Are Healthy and Others Not (1994). Finally, my scholarly involvement in issues of health policy was influenced by both my five years (1980-85) as the editor of the *Journal of Health Politics, Policy and Law* and my role as director of Yale's post-doctoral program in health policy and social science from 1993 to 2003.

8. I have been a fellow of the Institute of Medicine for some time and was in the early 1980s a founding member of the National Academy of Social Insurance. I am on the board of a number of health and public policy journals, as noted in my vita. I have listed in that vita the cases in which I have served as an expert witness during the past four years. These cases have involved public awareness of asbestos, disputes about the proper scope of Canadian national health insurance, and questions about the Medicare statute's policy toward the financing of durable medical equipment.

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9. I have done research on--and taught about--a wide variety of policy issues. This has included analyses of the legislative origins of Medicare, the struggle over what kind of outpatient drug benefit would be added to Medicare, and disputes over why the Clinton health care reform proposal failed as reform. I have studied regulatory struggles among government actors, physicians, hospitals, pharmaceutical industry manufacturers and other parties involved. Quantitatively, I have been the author, co-author or editor of eleven books and the author or co-author of over 150 articles in peer-reviewed journals and other academic publications. In that work, I have combined the diverse disciplinary methods of history, political science and policy analysis to address controversial descriptions, explanations, and evaluations of public policy developments in the welfare state area generally and in health policy more specifically. In doing so, I have used the methods of political science in constructing accurate and adequate descriptions of government policy-making and non-action. I have relied upon models of political analysis that clarify what policies are, why they emerge as they do (or not), and what implications follow from the structure of American government and politics for the prospects of continuity and change in established program practices. I have employed these models in my consulting to governments, corporations and not-for-profit organizations.

10. I have also worked in government and in roles directly related to governmental policymaking. This started in 1966 when I was a special assistant to Wilbur Cohen, then Undersecretary of the U.S. Department of Health, Education and Welfare, during the first summer of the Medicare and Medicaid programs. That experience was important in my writing of the Medicare book previously noted. I later

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served as the principal consultant to the President's Commission on Income Maintenance (1968-70) and a member of President Carter's Commission on an Agenda for the 1980s. Between 1982-84, I was the principal social and health policy advisor to Walter Mondale during his presidential campaign.

11. I have served as a consultant or advisor on health and other social welfare issues to federal agencies, congressional committees, and state governments, and I have testified before state legislatures and various committees of the United States Congress. I have been consulted by pharmaceutical firms about a variety of issues. Schering Plough hired my colleague Professor Jerry Mashaw and me to help interpret the meaning of the Clinton health reform for its firm in 1993. With Astra Zeneca, the task in 2003 was to explain current and anticipated public policy changes in Canada and the United States to its governmental affairs officials and to lead a conference on the subject in June of that year. Merck officials hired me in the mid-1990s to speak to their senior staff about the likely shape of regulatory policy toward their industry. In addition, I have testified on behalf of Canadian public authorities (federal and provincial) in connection with defending the provisions of the Canada Health Act of 1984. This included testimony before both New Brunswick and Quebec courts and, in the case of the latter, subsequent constitutional litigation in the 2005 Chaoulli case.

IV. Compensation

12. For my work in preparing this report, the Crescent Group will be compensated in the amount of \$30,000 by the State of California and VAC.

V. Principles, Methods, and their Application

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13. To address the questions posed at the outset of this report, I will proceed as follows. First, I describe the methodology that I apply to answering the questions posed. To describe and explain such policy developments over time requires selecting among and employing appropriate analytic models. The work of Graham Allison is fundamental here; the question to which his framework of analysis speaks is most simply put: “How should [one] try to understand the actions of ...government?”¹ Following the methodology described below, I then offer my views about what constitutes, and best explains, the policy history of Medicare and Medicaid generally. I will in turn, and in more detail, address the programmatic history of drug benefit reimbursement policies and practices. Finally, I will address some specific aspects of the Medi-Cal program and the context in which it operated to answer question 3.

14. To understand the origins and evolution of government programs--like Medicare, Medicaid or Medi-Cal--the analyst has to choose among or try to combine differing models of analysis. As noted in the political science literature, one widely employed approach is to treat the government of the United States (or nation, state or large collectivity) as if policymaking were the choice of an individual selecting a course of action among competing options according to clear purposes and evaluative criteria. Looking at Medicare and Medicaid through that particular analytic lens prompts this question: why did American government *choose* a hospital and physician insurance program like Medicare and a federal-state welfare program like Medicaid to finance the costs of medical care in 1965? As noted in my book on Medicare, thinking about a

¹ Allison, Graham T., Essence of Decision: Explaining the Cuban Missile Crisis, (New York: Harper Collins, 1971). Also, Allison, Graham T. and Zelikow, Philip, Essence of Decision: Explaining the Cuban Missile Crisis, 2nd Edition, (New York: Longman, 1999): viii.

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government as a unitary, purposeful actor is not uncommon.² The vocabulary of clear goals, rational calculation, and choice in governmental decision-making can transform unwieldy complexity into manageable packages. The presumption of a rational, unitary actor has a distinctive logic of explanation: “if a nation [or agency] performs an action of this sort, it must have had a goal of this type.”³

15. But such “simplification--like all simplifications--obscures as well as reveals.”⁴ The *unitary actor* approach--what Allison terms Model I--does not take into account that American government is in fact quite complex. What we call American government is, from another interpretive standpoint, a varied and loose association of large organizations with routines, standard operating procedures and subunits that can have quite distinctive--often competing--understandings of their purposes and practices.

16. The second approach--called the *organizational process* model--is sharply different. This second model takes large scale government bodies and programs as the units of analysis. The explanatory presumption is that organizations change slowly, that “the best prediction of what will happen at (time) $t+1$ is (what is happening at time) t .”⁵ Accordingly, predictions proceed from the structure, programs, and past behavior of the organizations whose actions are the object of description, explanation, and evaluation. It is obvious that this second model emphasizes both path dependency and inertia. Most social scientists recognize “such collectivities do not behave like individuals.

² Marmor, Theodore, *The Politics of Medicare*, (New York: Aldine De Gruyter, 1970, 1973, 2000): 64-67.

³ *Essence of Decision: Explaining the Cuban Missile Crisis*, 2nd Edition (1999): 5.

⁴ *Essence of Decision: Explaining the Cuban Missile Crisis*, 2nd Edition (1999): 3.

⁵ *Essence of Decision: Explaining the Cuban Missile Crisis*, 2nd Edition (1999): 175.

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Organizations filter information in ways persons do not. They seek means to maintain themselves over time not characteristic of individual behavior.”⁶

17. The explanatory implications of Model II are substantial. The “conjunction of the routine behavior of many individuals in organizational settings” explains “results in public policy” which cannot be accounted for by reference to the activities of dispersed individual parties or a unitary actor called the government. This second model is particularly relevant to analyses of governmental behavior in areas where the reliable performance of organizational routines and practices is crucial.⁷

18. Allison’s third approach--Model III-- has come to be known, somewhat misleadingly, as *bureaucratic* (or more recently, *governmental*) *politics*. The question the third model addresses is not what best describes and explains the behavior of governmental organizations over time. Rather, its focus is why actions at any one time emerge from bargaining episodes among individual players in positions of differential authority, persuasiveness, and power. In such bargaining analyses, the issue is why actors in various roles within the government produced particular actions--the policy choices best understood as resultants. It emphasizes how these resultants emerge from the exercise of skill, power, and advantage in contexts constrained by what various actors regard as the rules of the game.

19. Each of these approaches--frameworks, models, or lenses as their expositor Graham Allison writes--direct the analyst’s attention differently. The first highlights the costs and benefits of particular options and presumes that what the

⁶ *The Politics of Medicare*: 68.

⁷ An example would be the central importance of regular, reliable, and computer assisted reimbursement in both Medicaid and Medicare. State programs need to assure availability of drugs which, in turn, requires regular payment to pharmacies for tens of thousands of drugs and millions of individual transactions.

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government selected was a purposeful decision. Equally, if and when any policy emerges, Model I provides a rationalistic explanation of why that was so: a policy is understood as the appropriate means to the results that followed. But, such explanations may well be (and often are) factually inaccurate. Or, the result may have been an unintended consequence of the policy decision, or largely accidental. Only historical investigation can show what the policy aims and actions were, and were not. As Allison has clearly explained,

the shift from Model I to the Model II and Model III forms of analysis really involves a fundamental change in intellectual style. From the basic conception of happenings as choices to be explained by reference to objectives (on analogy with the actions of individual human beings), we must move to a conception of happenings as events whose determinants are to be investigated according to the canons that have been developed by modern science...Model II and Model III summarize two bundles of categories and assumptions, and two distinctive logical patterns that provide useful emphatic shorthands in which governmental action can be explained and predicted.⁸

20. It is plain that the defendants' claim in this case is illustrative of the restrictive, often misleading Model I mode of reasoning. Consider the defendants' proposition that the Federal Government and/or Medi-Cal acquiesced in the misconduct alleged in the complaint.. Their position appears to be that, if the "Government", writ large, "knew" about the pricing practices of the pharmaceutical industry in general, then its "failure" to change the AWP and related policies constituted governmental acquiescence in such pricing practices.⁹

21. Applying the organizational process model (Model II) directly challenges the notion of a unitary American government's decision-making mode, as well as the

⁸ Essence of Decision: Explaining the Cuban Missile Crisis (1971): 255.

⁹ See, e.g., Deposition of Charles Rice, Dey CEO..

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interpretation of the meaning of such supposed unitary decisions. To the contrary, Model II accounts would proceed along the following interpretive lines: If the federal government already had a standard policy of paying for drugs that was regarded as reasonably satisfactory,¹⁰ its dispersed organizations (Health Care Financing Agency-Center for Medicare and Medicaid Services (HCFA-CMS), the House Ways and Means Committee, the House Commerce Committee, the Senate Finance Committee, the Office of the Inspector General (OIG), the Government Accountability Office (GAO, et al.) would be expected to maintain (or simply continue) that policy until and unless a large scale change in the political environment precipitated an overhaul in policy. Equally, a policy on which a state Medicaid program relied would be constrained by formal federal requirements, the expectations of state legislators about controlling administrative costs, and the calls for reliable payments to druggists that the state legislature would demand.

22. For the analyst employing the organizational model, then, it is not enough to note the presence of drug reimbursement problems, allegations of fraud, evidence of individual misdeeds, or public complaining by individual actors and agencies. This body of evidence does not establish either what reimbursement policy in fact was or whether the continuation of particular practices constituted acquiescence or approval. There are large analytical gaps in the reasoning here. On the one hand, there was the government's limited understanding of random and hidden price disparities during the relevant period. On the other hand, there was the drug industry's targeting lobbying, designed to alarm the

¹⁰ "Reasonably satisfactory" is not a self-defining expression. The requirement of maintaining regular payments to pharmacies meant that state Medicaid and federal Medicare officials had, when available technically, to use computerized claims processing. That, in turn, required under the estimated acquisition cost regulation (EAC), timely submission of transaction prices. Since there was not an available, operational alternative to using the drug industry compendia as a source of price data, the use of reported AWP and WAC prices was the obvious recourse. Virtually every state did so.

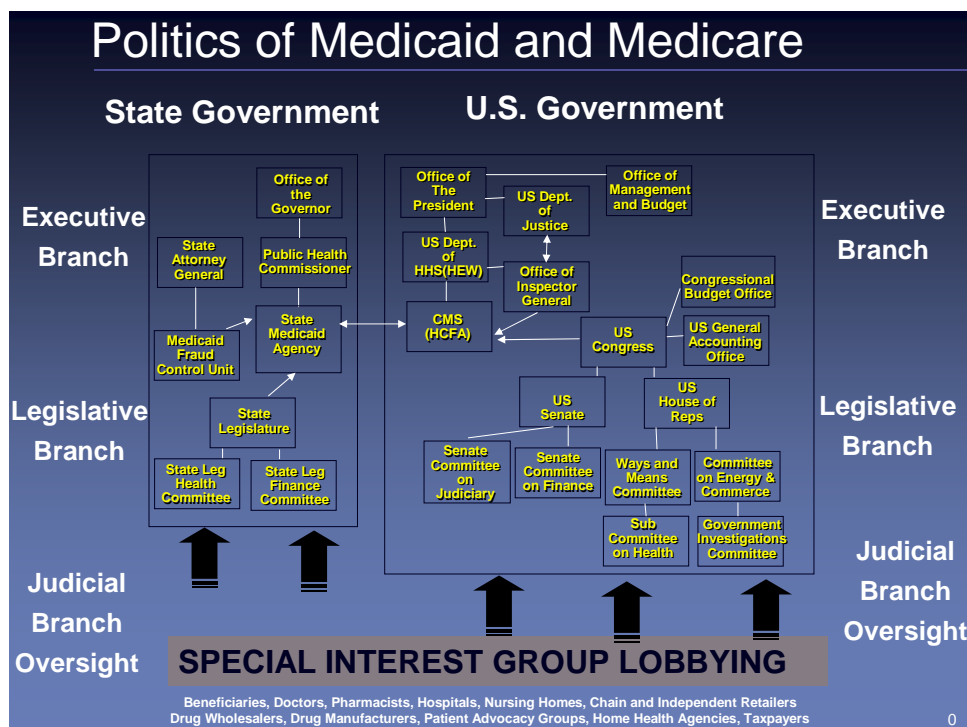
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congress and to convince members that reductions in reimbursement would make participation by pharmacies and physicians economically infeasible. Then there is the general lack of awareness of the extent of manipulation through inducements, affecting medical judgment. Finally, there is the drug industry's puzzling conclusion that the government's continuing use of reported prices constituted endorsement of these attributes of the reimbursement system. More direct, particular evidence of formal authoritative approval would be required, according to the organizational process model, to establish governmental acquiescence in the type of drug price reporting conduct alleged in this case. Nothing I have seen indicates that federal or state policymaking organizations did so.

23. By contrast, the model of governmental bargaining (Model III) would require even more detailed evidence to establish affirmative approval of the drug pricing practices at issue in this case. Again, continuing practices that were recognized to reflect some overestimation of costs--instead of risking reimbursement below costs--is a far cry from endorsing the type of conduct alleged in this case. To substantiate acquiescence, informed officials in authoritative positions would have had to have decided--in a bargaining discussion about competing options--to change the regulatory standard and, over time, to acknowledge such a policy position repeatedly. The historical record I have reviewed, as will be discussed below, is not consistent with that interpretation either. In the historical narrative section of the report, I will illustrate the use of these descriptive and interpretive models in reviewing factual claims about the evolution of governmental reimbursement policy.

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24. It is important to add to these methodological comments the following. These models are particularly relevant to understanding the structure and functioning of American government. American government is comparatively very complex, a system of institutions sharing power and authority both at the national level and across state and local boundaries. The chart below is a simplified sketch of the major institutions of American government associated with healthcare policy.



The dispersion of policymaking authority is obvious in the case both of Medicare and Medicaid, though the institutions sharing in that complex decision making differ between the two programs.¹¹ The dispersal of authority in the United States makes concerted, collective action more difficult than in a unitary state with parliamentary control, as in

¹¹ Note that the Social Security Administration had responsibility for Medicare until 1977 while the HEW's Social and Rehabilitation Services administered Medicaid from 1966 until the creation of the Health Care Financing Administration (HCFA) in 1977. Thus, to speak about the "government" doing anything during this time period regarding drug reimbursement understates the dispersal of administrative authority over these programs.

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most modern democracies. That much I will also try to illustrate more fully in the course of the following historical portrait of policy evolution.

VI. Medicare and Medicaid: Program Purposes, Policies Adopted, Explanations

25. To understand the evolution of reimbursement policies in these two substantial programs of public financing of medical care requires attention to their origins. It is crucial, for instance, to appreciate how unexpected these 1965 reforms were in medical care financing. Formally known as Title XVIII and XIX of the Social Security Act, the combination of Medicare's Part B and Medicaid were last-minute and utterly surprising additions to the hospital financing plan that had been debated for some years. The Johnson Administration had proposed in January of 1965 a hospital insurance program for the elderly (what became Part A of Medicare). Former opponents supplemented that familiar proposal with physician insurance (Part B) and added Medicaid as a third "layer" to what came to be called a "three layer legislative cake."¹² The financing and regulation of the two Medicare parts dominated the debates between the innovative proposals of March 1965 and the enactment of Titles XVIII and XIX in June of that year. The Medicare titles were entirely new; the Medicaid structure began with an historical legacy. What did that mean for the assumptions about paying for hospital, medical, and drug expenses?

26. What we now call Medicaid built upon and substantially expanded the Kerr-Mills program of 1960, which had provided limited federal subsidies to the states to finance health care for the poor among America's elderly. Medicaid took that model of

¹² The Politics of Medicare: 49-53, 60.

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“welfare medicine” and added coverage for the “categorically needy”: the blind, the disabled and children from poor families.¹³

27. The surprising enactment of Medicaid meant that its policies--reasoning from the organizational process model--reflected consequential legacies from early welfare programs on the one hand and what HEW officials generally assumed were workable, accepted policies toward reimbursement on the other. Familiar organizational ways of thinking, in other words, were central to what was proposed and acted upon.

28. This is crucial to note because the Medicare statute itself did not substantially address the reimbursement of drugs at all.¹⁴ From 1965 to 2005, outpatient drug expenses were not generally covered, though in the 1980s there was considerable discussion of that fact.¹⁵ On the other hand, Medicaid from the outset had a broader benefit package, including paying for drugs. Nonetheless, drug reimbursement received little attention in the crowded period between the emergence of the three layer cake proposal in March of 1965 and the enactment of Medicare and Medicaid in late June of that year. Drugs were not a major feature of medical care expenditures in 1965 and correspondingly got little attention in this unexpected Medicaid innovation.¹⁶

¹³ The health status of America's poor--especially poor children--in the mid-1960's is hard to imagine today. Jonathan Engel's book chronicles a number of shocking reports of the era. One on children's health in rural Mississippi in the early 1960s found "in child after child...evidence of vitamin and mineral deficiencies; serious, untreated skin infections and ulcerations; eye and ear diseases, also unattended bone disease secondary to poor food intake, the prevalence of bacterial and parasitic disease...children afflicted with chronic diarrhea...leg and arm injuries and deformities." Another in Kentucky discovered that "children displayed skin ulcerations, tooth decay, open sores, boils, abscesses, impetigo, rat bites, and hookworm." And a House Ways and Means Committee investigation concluded "that half of all children in the United States under the age of fifteen had never been to a dentist." Engel, Jonathan, Poor People's Medicine (Durham: Duke University Press, 2006): 49, 74-75.

¹⁴ From May, 1967 until February, 1969 a HEW Task Force on Prescription Drugs undertook a "comprehensive study of the problems of including the costs of prescription drugs under Medicare." See Task Force on Prescription Drugs: Final Report, 7 February 1969.

¹⁵ Oberlander, Jonathan, The Political Life of Medicare (Chicago: Univ. of Chicago Press, 2003): 60.

¹⁶ Ibid at 46. The detailed account of how Medicare's Part B and Medicaid got added to the original proposal of hospital insurance in 1965 is the subject of chapter five of The Politics of Medicare.

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29. Medicaid emerged where the Kerr-Mills program was thought to have failed. In 1962, when some 35 million Americans were living under the poverty line, Kerr-Mills covered less than 150,000 of America's elderly poor, with most of its expenditures in only five states.¹⁷ The remaining low-income Americans--if they did receive needed care--depended upon physician, private hospital and pharmacist charity, or free care in public hospitals.

30. At its most expansive, the Kerr-Mills program financed the medical care of less than 200,000 citizens. By 1967--only a year after enactment--Medicaid covered over 7,000,000 Americans. Its core benefits--the costs of which quickly became a concern--were payments to hospitals, nursing homes, and physicians. Medicaid--like Medicare--set out to pay hospitals their "reasonable costs," proceeding from standard practices in the Blue Cross world of private hospital insurance. In the case of physicians, Medicare's legislative language called for reimbursing "usual and customary" fees.¹⁸ For Medicaid, neither physician--nor prescription drug--reimbursement was legislatively specified.¹⁹ Prescription drugs, an optional benefit, were in the first years of the program a modest and largely unnoticed component of spending.

31. By comparison, there was considerable attention given to an acceptable general policy toward reimbursement issues in the struggle over Medicare's provisions. In the hospital sector, the legislation reflected a carryover from the dominant mode of financing used by the Blue Cross plans at that time: reimbursement of what were

¹⁷ Stevens, Rosemary, Welfare Medicine in America (New Brunswick: Transaction Publishers, 2004): 33.

¹⁸ See The Politics of Medicare (2000): 89.

¹⁹ Rosemary Stevens in Welfare Medicine in America at pg. 66 interprets the differing standards in the following way: "presumably 'reasonable cost' ... would bear a direct relationship to the actual cost of services provided... For other services provided under Medicaid, states could, however, choose their own formulae and set their own payment schedules. These alternatives could include the long welfare tradition of reimbursing at less than cost, in other words, expecting providers to donate out of charity."

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thought to be “reasonable costs.” The understanding then was that Medicare would democratize access to health insurance by mirroring for the elderly what was available to a large proportion of working Americans through employer-financed hospital insurance. The legacy was cost-based reimbursement and the legislation promised precisely that. In the case of physician payment, there was no established government or non-governmental model as dominant as Blue Cross in the hospital sector. Blue Shield plans distinguished between indemnity payments for some insured and fee schedule reimbursement for low-income families. For reasons outlined in The Politics of Medicare²⁰ simply carrying over the Blue Shield model was rejected legislatively. Instead, the 1965 Congress enacted a standard of “reasonable charges” – i.e., charges based on what was described as “usual and customary” fees.

32. The history of disputes about what “reasonable charges” meant in practice is not the focus here. But one should note that this payment standard for physicians mirrored the hospital reimbursement policy--i.e., paying what hospital care costs generally or what physicians typically charged their insured patients. This perspective--paying actual costs or market prices--carried over to the pharmaceutical area, but with far less legislative and executive attention. For Medicaid, whose reform was the most unexpected, the presumption was that the program offered financial support to hospitals, doctors, and druggists who otherwise were asked to provide charity care, services, and goods to poor people unable to pay (in full or at all) for their medical care needs. To the extent Medicaid payments subsidized a set of beneficiaries with more

²⁰ The Politics of Medicare (2000): 89. The legislation borrowed instead from the commercial insurance practice of the time in the reasonable charge standard, with Aetna’s plan for federal employees as the particular source.

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expanded financing than they enjoyed before, the program was thought to benefit both poor patients and their medical care providers.

33. It is important, however, to recall that the late 1960s context for both Medicare and Medicaid quickly became one of intense concern about medical inflation. A key focus of concern was the cost-based reimbursement policies with which both programs began.

34. The principles of cost-based and charge-based reimbursement were not accidental. Interest groups representing health provider groups had lobbied for such a model. They were intent that Medicare and Medicaid would finance, not regulate, the prices of medical care. However odd that might seem in 2008, when the federal role in shaping the economics of medical care is so significant, no such presumption prevailed in the 1960s. Indeed, the Pharmaceutical Manufacturers Association had argued in 1965 congressional testimony against any federal action that “would be tantamount to price setting...and a denial of normal market mechanisms.”²¹

35. In Medicaid, a combination of higher than expected enrollment and greater than expected expenditures per beneficiary caused severe budget pressures and heightened political attention. Amendments to the Social Security Act in 1967 limited program enrollment growth; it also empowered the Secretary of Health, Education, and Welfare to use “methods and procedures to safeguard against payments in excess of reasonable charges for drugs consistent with efficiency, economy, and quality of care.”²² This tension between budget pressures and service aims was to be a recurrent

²¹ “Statement of Austin Smith, MD, President, Pharmaceutical Manufacturers Association (PMA),” U.S. Senate Committee on Finance, 13 May 1965, 760.

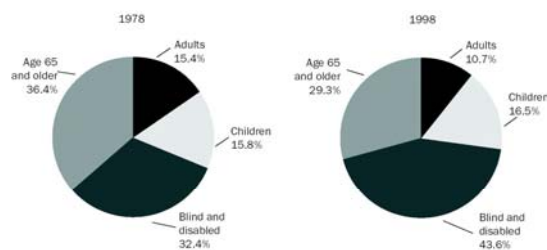
²² “Reimbursement of Drug Cost: Medical Assistance Program,” Federal Register, 27 November 1974: 41480.

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theme in Medicaid's and Medicare's history. The aim of helping disadvantaged populations gain access to care clashes with budgetary constraints on enrollment, and payment demands by providers of care.

36. Today, Medicaid is the largest government program in most if not all states, and one of the largest federal programs. More than fifty million citizens benefit; a third of U.S. births and half of nursing home expenditures are paid for by Medicaid.²³ There has been a slight shift in the composition of the covered low income population away from adults, and toward children and the disabled. (See Exhibit 1).

EXHIBIT 1 Distribution Of Medicaid Payments By Eligibility Group, Fiscal Years 1978 And 1998



SOURCE: HCFA Form 2082 data (now the Centers for Medicare and Medicaid Services, or CMS).
NOTES: The percentage distribution for 1978 does not include \$1.4 billion of payments (in 1998 dollars) on behalf of 1.9 million people served by Medicaid whose basis of eligibility is reported as "other," and the percentage distribution for 1998 does not include \$3.7 billion on behalf of 3.1 million people served whose basis of eligibility is unknown. Percentages may not sum to 100 because of rounding. "Payments" describe direct Medicaid vendor payments and Medicaid program expenditures for premium payments to third parties for managed care (but exclude disproportionate share hospital payments, Medicare premiums, and cost sharing on behalf of dually eligible beneficiaries). The term "adults" as used above refers to nonelderly, nondisabled adults. Disabled children are included in the "blind and disabled" category above.

Bruce C. Vladeck,
Where The Action Really Is: Medicaid And The Disabled,
Health Affairs, Vol 22, Issue 1, 90-100

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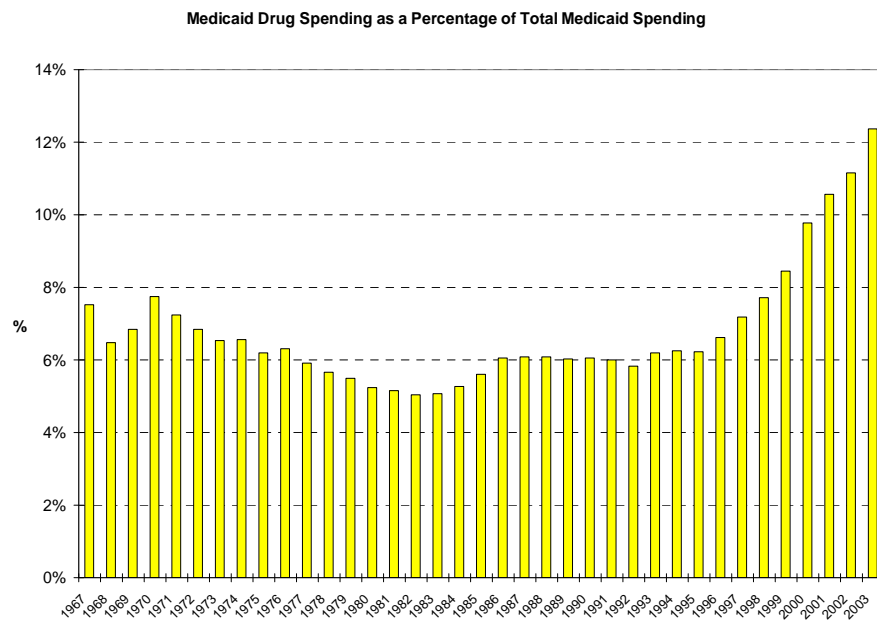
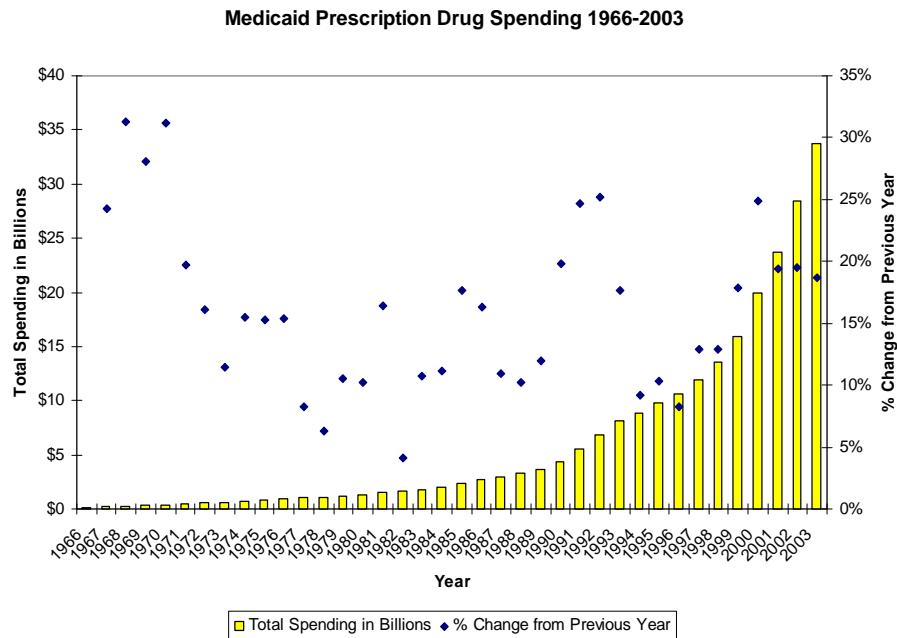
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37. As noted, Medicaid spending on pharmaceuticals began as modest outlays. But, over time, drug spending increased well beyond general inflation, as the charts below show. Drugs now constitute a very substantial portion of Medicaid expenditures.²⁴

²³ Iglehart, John, "The Dilemma of Medicaid" *New England Journal of Medicine*, 348:21 (22 May 2003), 2140-2148.

²⁴ With the implementation of the Medicare Modernization Act of 2003--a development after the time period of this case--about half of such drug expenditures were shifted to the Medicare program.

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Sources: (Drug Spending) 1966 Comptroller General Memo; 1967-1974 US House of Representatives Report; 1975-1989 HCFA Medicaid Source Book; 1990-1998 HCFA 2082 Reports; 1999-2003 MSIS Reports. (Total Spending) Medicaid Financial Management Reports; CMS -64 and predecessors

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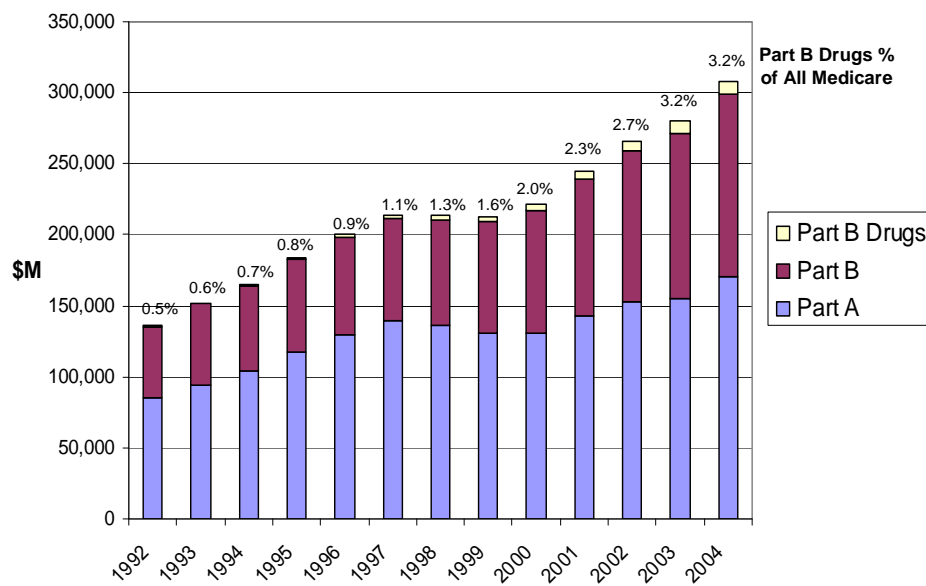
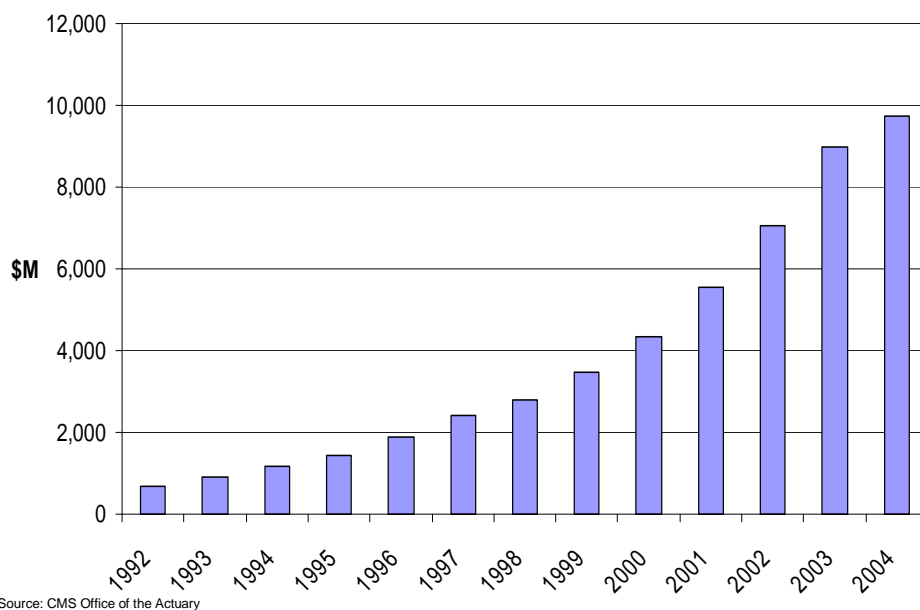
Notably, California's prescription drug spending tracked that of Medicaid in the relevant time period, with relatively modest increases in the 1990s and a significant spike upwards starting in 1999.²⁵

Year	Total Claim Reimbursement Amt
1991	\$718,825,681.44
1992	\$887,333,632.09
1993	\$1,032,708,543.99
1994	\$1,162,571,672.69
1995	\$1,187,845,076.83
1996	\$1,291,674,801.66
1997	\$1,441,016,956.28
1998	\$1,691,739,944.16
1999	\$2,067,241,609.21
2000	\$2,532,613,048.46
2001	\$3,085,342,064.84
2002	\$3,707,283,894.96
2003	\$4,282,713,899.20
2004	\$4,847,185,892.48

38. As the next chart demonstrates, Medicare spending increased very sharply in the 1990's, but more so under Part B than Part A. Part A's drug expenditures are those generated during a hospital stay and are not separately reimbursed by Medicare. That means the cost of the drugs prescribed is what the hospitals negotiate separately. Part B, by contrast, reports its budget outlays for drugs: the drug bills paid by Medicare directly to doctors and pharmacies subject to the program's drug reimbursement policy. It is notable that the drug expenditures for Part A were relatively obscured during this time period, compared to the substantial and visible increases in Part B outlays for drugs.

²⁵ Source: Medi-Cal Pharmacy Benefits. *See also* <http://www.dhcs.ca.gov/dataandstats/reports/Pages/MCalDrgUtilData.aspx>.

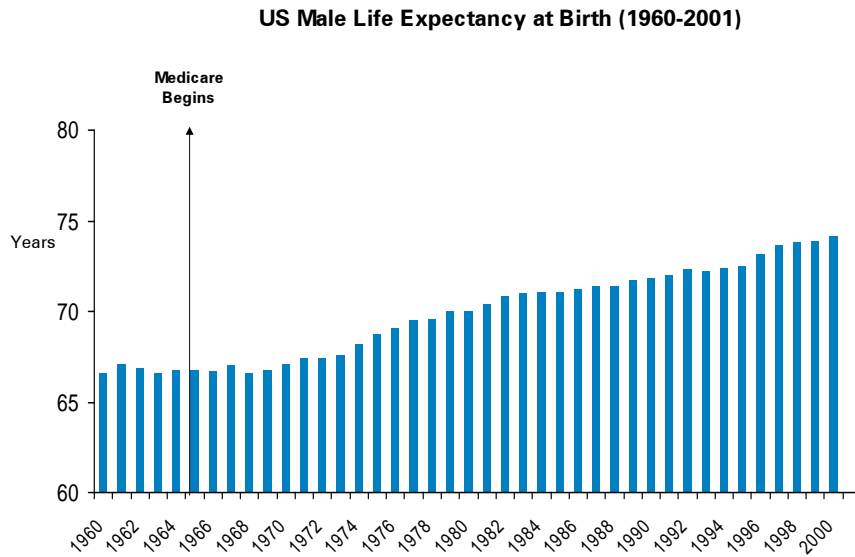
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Medicare Spending**Medicare Pt. B Drug Spending**

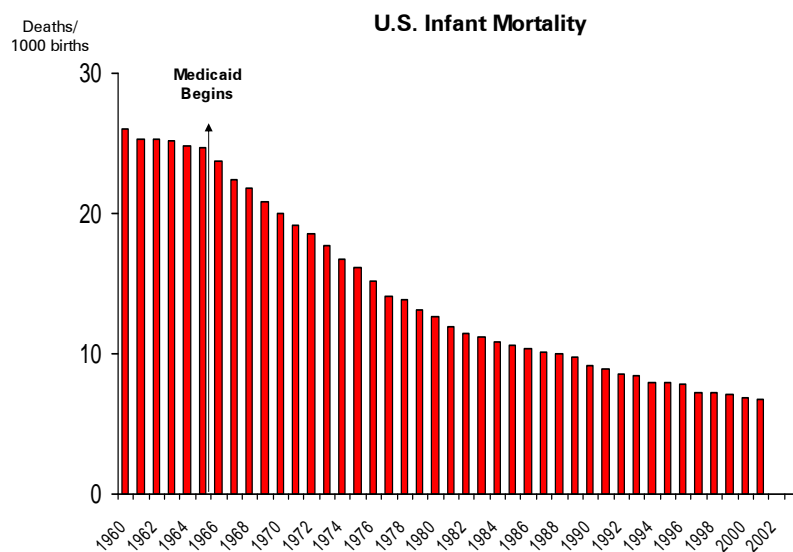
39. A separate question is whether Medicare and Medicaid expenditures have produced good value for the money spent. Have they improved the public's health as well as cushioning the financial impact of sickness and injury? The data available

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suggest a positive answer. Improvements in life expectancy and reductions in infant mortality have taken place during the life of these programs. The correlations do not settle the case for causality, but they support the causal presumption.



Source: OECD Health Data, 2003



Source: OECD Health Data, 2004

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VI. Medicaid Drug Pricing Policy and Politics

40. The history of Medicaid prescription drug policy and politics had, until quite recently, received relatively little scholarly attention. Rosemary Stevens' 1974 case study of Medicaid, *Welfare Medicine in America*, mentions some conflicts over drug policy, but makes no mention of reimbursement conflicts. Jonathan Engel's more recent and comprehensive program history, *Poor People's Medicine*, (2006), barely touches on the topic of prescription drugs. What was important to governmental officials--and the pharmaceutical industry--did not play an important role in the journalistic or scholarly commentary about Medicaid.

41. As a result, one has to put together a historical understanding from quite varied sources: government agency rule making and reports, congressional hearing transcripts, the journal articles of stakeholder groups, and scant newspaper coverage. The implication is that the story of Medicaid's reimbursement policy is complicated, with different actors holding substantially different ideas about what was taking place, let alone what was desirable. To understand what stakeholders were doing over time one has to investigate what they said, what they claimed, what they thought they knew, what confused them, and what options for action they in fact had.

42. With this approach in mind, I turn to the policy history as reflected in the available historical record and organized through the conceptual lenses of Models II and III.

A. 1967-84

43. The States--continuing Kerr-Mills practices--were given wide discretion in how they reimbursed drugs in their Medicaid programs during the period from 1967 to

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1974.²⁶ The federal Department of Health, Education and Welfare (HEW), while paying from 50 to 83% of Medicaid expenditures, delegated drug payment policy to the states. During that period, as the data show, there were very rapid increases in drug expenditures. Because the baseline drug expenditures were comparatively small, the total drug outlays appeared modest by comparison with hospital and physician expenditures.

44. In 1975, however, the issue of drug price inflation did come onto the policy agenda. HEW Secretary Casper Weinberger proposed federal regulations that prompted an outcry from the pharmaceutical industry. His initial proposal was to limit reimbursement for prescription drugs to their actual acquisition cost (AAC), plus a dispensing fee.²⁷ For generic (multi-source) drugs, the Secretary suggested a Maximum Allowable Cost (MAC) basis for reimbursement. Both of these proposals proved controversial.

45. First, commentators argued that governments did not have the technical capacity to determine actual acquisition costs on a timely and accurate basis. Secretary Weinberger, accepting this constraint and opposed to government price-setting on the model of most other developed nations, substituted estimated acquisition cost (EAC) for AAC.²⁸ This decision is unusual in comparative terms. Most industrial democracies

²⁶ It took over two years for any federal regulations to be developed in this area. HEW used an interim policy for drug reimbursement of "actual acquisition cost" ("Reasonable Charges: Notice of Interim Policies and Requirements," Federal Register, 16 July 1968: 10233-4), but after a comment period settled upon a policy of "cost as defined by a state agency plus a dispensing fee." ("Final Rule: Administration of Medical Assistance Programs: Reasonable Charges," Federal Register, 25 January 1969: 1243-1245).

²⁷ "Maximum Allowable Cost (MAC) for Drugs, Notice of Proposed Rulemaking," Federal Register, 15 November 1974 and 27 November 1974.

²⁸ "Final Rule - Limitations on Payment or Reimbursement for Drugs," Federal Register, 31 July 1975 and 15 August 1975. A vital aspect of Weinberger's alternative was an attempt to increase the capacity of states to acquire accurate data on market prices so close estimations of AAC could be derived.

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engage in bargaining with the pharmaceutical industry about what they are willing to pay for drugs rather than relying on market prices reported by the industry.²⁹

46. Weinberger maintained the original MAC provisions³⁰ despite opposition from the drug industry. (The final manifestation of that opposition came in the form of a lawsuit, which the plaintiffs lost.³¹) This began the complicated history of the government estimating what it cost pharmacies to buy drugs.

47. The HEW standard for payment of drugs was to be the lowest of three options: MAC plus a dispensing fee, the EAC plus a dispensing fee, or a pharmacy's usual and customary charge (UCC). This federal policy was not formally amended until 1987. As a result, federal policy during the period 1975 to 1987 sought to reimburse drugs on the basis of the pharmacy's (or chain's) cost of acquiring drugs, plus a separate dispensing fee.³²

²⁹ Jacobzone, Stephane, "Pharmaceutical Policies in OECD Countries," Four Country Conference: Pharmaceutical Policies in the US, Canada, Germany and The Netherlands, July 2000.

³⁰ A Pharmaceutical Reimbursement Board was created within HCFA to identify the multiple source drugs for which significant federal funds were spent and then to develop a MAC for each. The Board set the MAC at the "lowest unit price" at which the drug was generally available. In 1987, this was changed to "150% of the published price for the least costly therapeutic equivalent."

³¹ "Pharmaceutical Industry Sues HEW on Government Drug Price-Setting Program," PMA Newsletter, 27 October 1975: 3.

³² These dispensing fees had some obvious justification. When filling prescriptions, pharmacy businesses incur costs beyond the price of the drug itself. These include expenses such as pharmacist and other employee wages, utilities, rent and overhead. Dispensing fees are paid when pharmacists are reimbursed on an EAC or MAC basis. It has not applied to funding drug costs on a UCC basis, where the cost of dispensing is built into the charge to the paying customer. From the perspective of academic policy analysis, however, there is no single, accepted, correct way to compute actual dispensing costs. There are contested questions that attend this task: the allocation of overhead, for example, how to deal with negative and positive externalities, and the computation of an enterprise's average as opposed to marginal costs. This means that there is an irreducible uncertainty about what counts as the right dispensing fee. On the other hand, what pharmacists are willing to accept from other payers--rather than declining the business--is one basis for calculating an appropriate level of payment.

The Medicaid program has never agreed to finance excess reimbursement for ingredient costs in order to make up for any shortfall in dispensing fees. The documentary record shows clearly that separate provisions were designed and implemented for each type of expense reimbursement. Both components were to be reimbursed independently of one another.

The policy for Medicare has been analogous. Significant efforts have been made to reimburse providers for their cost of administration for "incident to" drugs. No "cross-subsidy" policy ever existed.

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48. The processes by which the overall payment policy emerged made clear what was not done. Weinberger noted the “number of comments [contending] that the policy amounted to ‘price-fixing’ or interfered with ‘free enterprise.’ ” He made plain his support for using market prices rather than governmental market power to set prices at which HEW would reimburse pharmacies. He “disagreed” with the claim that HEW was setting prices. The regulation, Weinberger asserted, “does not control marketplace activity, but rather takes advantage of the varying drug prices which are established by and exist within the marketplace...upper limits ...will continue to be determined by marketplace activities.”³³

49. The decision to refrain from any sort of government “price setting,” was important. Relying instead on what were claimed to be market prices in setting governmental reimbursement produced serious problems. States had but two major sources of information for estimating drug prices: the data provided by HEW and the annual Red and Blue Book “compendia.” The HEW relied upon drug price information from the presumed market leader, IMS Health. IMS data, it turned out, overstated actual drug acquisition costs. By 1984, the Office of the Inspector General (OIG) recommended against using their pricing data. The 1984 report also suggested that the prices reported in the Red and Blue Book compendia were, for the drugs studied, in excess of actual acquisition prices.³⁴

³³ “Final Rule - Limitations on Payment or Reimbursement for Drugs,” Federal Register, 31 July 1975: 32289.

³⁴ “Title XIX of the Social Security Act, Limitation on Payment or Reimbursement for Drugs,” HHS OIG Report, 1 September 1984. I am aware of the historical disputes about how the expression AWP was employed. It was part of the rhetorical record, with different actors claiming to have a unique understanding of the practice--as opposed to the dictionary definition of the words, or plain, ordinary meaning. The historical record does not show evidence of any government statute, regulation, or official pronouncement stipulating a distinctive--i.e. different from the dictionary-- meaning of “average wholesale price.”

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B. 1984-90

50. The 1984 OIG report touched off political debate among those attentive to pharmaceutical issues and generated considerable confusion. The consequent dispute--and the confusion generated--undercut the OIG's weight and authority. Interest groups, especially retailers, barraged Congress with studies and testimony. They reiterated the same theme. Discounts from AWP prices might be available to some, the trade association contended, but not all, retailers. Critics also challenged the methods the OIG study used, including doubts about the generality of their findings. Some federal legislators defended AWP reimbursement itself, which made changes in formal policy more difficult. In 1985, the National Association of Retail Druggists President claimed publicly a lobbying victory for continuation of the AWP basis for reimbursement.³⁵ One phase of the political bargaining story was over. An effort to change the AWP standard was defeated – and with the explicit support of pharmacy and drug manufacturing trade associations.

There has been considerable attention to the margins wholesalers charged over time. E. Berndt, for example, observes that as the drug wholesale industry consolidated over time, margins that once approximated 20 or 25% fell to 3 or 4%. (See "Report of Independent Expert Professor Ernst Berndt to Judge Patti B. Saris," United States District Court District of Massachusetts, 9 February 2005). This report of industry practices does not, however, settle who knew what, when and where about those practices. This is especially noteworthy in a context where pricing data was treated as confidential. In the historical record, I found little, if any, recognition by HCFA or CMS officials of the changes in wholesaler margins.

Manufacturers continued to report and pricing compendia continued to publish a historical markup that no longer existed. I cannot conclude whether this was "understandable...and not the result of any sinister or nefarious conspiracies" – as concluded by Berndt. But, one thing is clear: the customers of the manufacturers and wholesalers reaped the benefit of the practice, while Medicare and Medicaid bore the cost. (There was indeed some evidence of industry collaboration on pricing matters during the period. See "Ruling in Price-Fixing Case Provides a Look at Drug Industry," New York Times, 14 April 1996).

³⁵ The NARD President called attention to the group effort to block legislative change: "Just as a coalition approach worked wonders in foiling the fed's attempt to eliminate AWP as a basis for Medicaid reimbursement," he warned, "unfair pricing will also require a coalition...NARD has talked with the National Association of Chain Drug Stores, the PMA, and the National Wholesale Druggists' Association. They are all 'supportive' of the idea in 1985." ("NARD leaders reveal alliance against differential pricing," Drug Topics, 18 November 1985: 68-69).

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51. At the same time, drug inflation continued undiminished. In the Congress there was optimism among some legislators that the availability of generic drugs would dampen inflation in this industry. In 1984, legislation--the Drug Price Competition and Patent Restoration Act--promised faster access to cheaper drugs.³⁶ The MAC program had been very disappointing, producing only twelve approved generic drugs in a decade. The new law on generics, many hoped, would generate savings for Medicaid. This was one policy development; there were others as well.³⁷

52. To achieve savings required Medicaid to approve payment for generic drugs at a faster pace than before. Policy changes were required. And in 1986, ten years after the implementation of the Weinberger regulations, there was indeed a new set of proposals for reimbursing drugs under Medicaid. The Secretary of the Department of Health and Human Services (HHS) offered three reform options.³⁸ Each encouraged greater use of generic drugs to reduce Medicaid's program expenditures. All suggested streamlining the process of qualifying generic drugs for program reimbursement. One option, the Pharmacist Incentive Program, called for financial incentives to pharmacists to substitute generic for brand drugs. A second, the Competitive Incentive Program, would have required pharmacists to give Medicaid price discounts from actual retail prices. But it would have allowed pharmacists to make--or lose--money from brand and generic drug sales.

³⁶ "Law Enacted to Spur Generic Drug Market," New York Times, 25 September 1984: Sec B5.

³⁷ Another development, to be discussed later, was what came to be called the whistleblower statute of 1986 and related programs to address alleged waste and fraud in governmental payments for goods and services.

³⁸ "Proposed Rule: Medicare and Medicaid Programs; Limits on Payments for Drugs," Federal Register, 19 August 1986 and 18 September 1986.

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53. In the end, however, HHS officials did not go ahead with any of these options. Intense objections by state governments, pharmacists, and drug manufacturers played a role.³⁹ The result was that certain problems were once again highlighted, but overall drug reimbursement policy was not substantially changed.⁴⁰

54. In the end, the HHS Secretary ended the MAC program and created an upper limit (FUL) on federal payments for two classes: multi-source and other drugs.⁴¹ For multi-source drugs, reimbursement was 150% of the lowest published price of the least expensive generic supplier. For single-source--called "other"--drugs, the final rule emphasized that "[T]he upper limit for other drugs...retains the EAC limits as the upper limit standard that state agencies must meet." But the rule was to be applied "on an aggregate rather than on a prescription specific basis."⁴² The standard for payment of drugs remained the lowest of three options: MAC (now called the FUL) plus a dispensing fee, the EAC plus a dispensing fee, or a pharmacy's usual and customary charge (UCC). But other changes were forthcoming.

³⁹ "Final Rule: Medicare and Medicaid Programs; Limits on Payments for Drugs", Federal Register, 31 July 1987: 28650.

⁴⁰ It should be noted that there were changes in the process of generic drug approval for Medicaid reimbursement. My point here is that the fundamental basis of reimbursement was reviewed, but not authoritatively altered. In addition, I found no evidence of a changed policy towards cross-subsidizing pharmacists. In short, the claim that in the 1980s the federal government's Medicaid officials accepted that pharmacists should be cross-subsidized by inflating acquisition costs is without empirical foundation. Indeed, HHS rejected proposals to have pharmacists increase revenues from sources other than the dispensing fees. This does not deny that pharmacy interests regularly promoted increased revenue, wherever it could be found. That is expected from interest groups in American politics.

⁴¹ "Final Rule: Medicare and Medicaid Programs; Limits on Payments for Drugs," Federal Register, 31 July 1987: 28650-53.

⁴² *Ibid* at 28653. Some have suggested the "in the aggregate" language in this regulation changed the policy to one in which the sum of ingredient cost and dispensing cost would be considered as the standard for payment. By this reasoning, it was legitimate to pay higher than estimated ingredient costs if lower than cost payments were made for dispensing fees. I have seen no evidence that such a policy was ever implemented or that such criteria were used for evaluation. In fact, after 1987, the OIG and GAO continued to judge program performance by looking at the gap between estimated and actual ingredient acquisition costs, not any gap between the sums of the two components.

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55. By 1989, HCFA had addressed some problems with AWP reimbursement. Federal policy, for instance, had rejected undiscounted AWP as a basis for estimating the acquisition costs of drugs for Medicaid. Federal officials made this explicit in a number of ways, including instructions by regional administrators to state Medicaid officials. A handful of states responded by moving to a wholesale acquisition cost (WAC) “plus” basis. Most states--despite their inability to determine actual market prices--chose to discount from reported AWP. They did so at varying levels and in varying ways, but always subject to the fear of losing federal matching funds. HCFA approved most of these altered state plans, with some disputed practices ending up in the courts.⁴³

56. Continued inflation in drug prices meant difficult choices for states. Some states tried quite different strategies to constrain drug inflation. All were of limited success, as prior charts have illustrated. Given budget pressures and constitutional limits on deficit financing, the continuing medical inflation meant that states had to restrict Medicaid eligibility, reduce the number of prescriptions, and/or increase patient cost sharing for drugs.

57. There was, in short, no absence of governmental efforts to cope with drug inflation. A number of states, as noted, explored different strategies for coping with drug inflation in the late 1980s. Some, for example, tried using formularies for certain classes of drugs, taking their cues from pharmacy benefit managers.⁴⁴ That instrument, then and now, is regarded by many observers as the most powerful cost control tool against drug inflation. As noted in a 1989 NY Times article, “The State and private health plans

⁴³ An exception was when a state tried to use undiscounted AWP as the method of estimating drug ingredient acquisition cost.

⁴⁴ Freudenheim, Milt, “Cutting the Cost of Medicaid Drugs,” New York Times, 30 Jan. 1990.

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[threatened] to drop some products from their lists of drugs approved for reimbursement.”⁴⁵

58. Another strategy was to use competitive bidding. Ultimately, thirty-seven states tried putting drug contracts out for competitive bid. But almost all had their negotiating efforts “blocked” by drug companies unwilling to provide bids.⁴⁶ One state, Kansas, eventually succeeded in obtaining a 30% price reduction but for only one drug. This outcome illustrates a continuing feature of the policy struggle over drug reimbursement. The drug industry on the one hand resisted any type of governmental price-setting for drugs. This in turn contributed to steady inflation in Medicaid pharmaceutical expenditures. On the other hand, the drug industry employed political, legal and economic strategies continuously to thwart efforts to address that inflation with different policies. This combination of defense and offense against stronger alternatives is a major, underlying theme of this report. This strategy was repeated even more vigorously in the 1990s. At no time, however, did the industry fully inform the government of its real prices for reimbursement purposes. Nor did it make clear through lobbying that it was promoting a system in which reported prices had no relationship to actual prices and generated questionable influence on medical judgment.

C. 1990-2001: Following three developmental channels

59. The explanation for the rapid increase of Medicaid’s and Medicare’s drug expenditures in the 1990s requires attention to developments that were at the time largely shrouded in secrecy, misrepresentation and contested investigative claims of wrongdoing.

⁴⁵ Freudenheim, Milt, “Price Revolt Spreading on Prescription Drugs,” New York Times, 14 November 1989.

⁴⁶ “Skyrocketing Prescription Drug Prices,” US Congressional Hearings and Majority Staff Report, 16 November 1989 and 1 January 1990.

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60. To make sense of this involves separate discussion of three streams of political and organizational activity. The first is the working out of the OBRA legislative bargain, a channel of action marked by a four year moratorium on reduction of Medicaid drug payment levels, a partial implementation of what I will term budgetary relief through rebates, and heightened attention by the HHS Inspector General's office over the decade to a variety of state experiences in reimbursing selected drugs.

61. The second channel differs substantially in origins and mode of activity. The elimination of "waste, fraud, and abuse"⁴⁷ had by the 1990's become a preoccupation in federal health programs. (See appendix one for a chronology of government anti-fraud laws relevant to this channel). The False Claims Act Amendment of 1986 increased the financial incentives for what are called "whistle blowers" to report alleged misconduct among firms whose products and services receive governmental funds. This development drew upon a different congressional source of authority (the Judiciary committees, not the Budget committees). Equally important, the Department of Justice (DOJ) and State Attorneys General became more important actors. That meant federal courts would be involved, but also state courts. And, even before DOJ's involvement, there were other developments in the legal arena: namely, federal statutes against kickbacks and provider self-referrals. This legalization of concern about provider misconduct expanded the channels through which public action took place. The rules of the legal world had important implications for how evidence would be uncovered

⁴⁷ Marmor, T. and Mashaw, J., "Conceptualizing, Estimating and Reforming Fraud, Waste and Abuse in Health Care Spending," Yale Journal on Regulation, 11 (1994) 1-35. It is revealing that after a serious review of the literature in 1993-94, the authors (including this expert) did not identify pricing fraud as a major area of fiscal concern or legal interest. Since the article was directed at what was known at the time, this bears on the degree to which it was known the actual pricing behavior deviated from what was reported.

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(slowly), what evidence would be permissible to introduce, and what counted as the definition of impermissible conduct. The role of a whistleblower--Ven-A-Care (VAC)--in promoting attention about drug reimbursement practices to congressional, DOJ, HHS, and state agencies is important in its own right. It also is a link to Medicare and Medicaid's place in drug reimbursement disputes in the 1990s.

62. The third channel, the involvement of Medicare in disputes about drug reimbursement, is complicated, both connected to Medicaid developments and separate as well. For most of Medicare's history, drug reimbursement was not, as noted, a major concern. Indeed, prior to 2005, outpatient prescription drugs were, in the main, not insured for Medicare beneficiaries. (Drugs delivered in the hospital or skilled nursing home (SNF) setting were insured through Medicare Part A, but not separately budgeted, as explained earlier). The only directly budgeted drug reimbursement was for services provided "incident to" physician care under Part B. By 1992, such payments totaled over \$600 million. But that sum constituted only one half of one percent of all Medicare expenditures, and about 1/10th of what Medicaid spent on drugs.

63. The way by which Medicare slowly addressed drug reimbursement had much to do with its relatively small role in the program's budget--and, accordingly, the greater attention to claims of fraud in the larger items of that budget: hospital and physician reimbursement. A combination of medical inflation, fiscal pressures caused by the budget deficits of the 1980s, and the recession of the early 1990s led some policymakers to focus on the Medicare program as well. And, by later in the 1990s, Medicare was to play a more prominent role in these disputes.

i. OBRA 90: Saving Money by Paying "Best Prices" for Medicaid Drugs?

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64. By 1990, Medicaid's payments for drugs were under public attack. The U.S. economy neared recession. Congressional hearings, led by Senator David Pryor (D, AR), drew press attention both to the fiscal impact of annual drug inflation and to the unwillingness of drug firms to cooperate with competitive bidding in Medicaid. He "introduced legislation...to help states control spiraling drug costs by negotiating prices with manufacturers."⁴⁸ The Bush Administration of 1990--prompted both by this legislative proposal and difficult fiscal circumstances--developed an alternative reform model. Their proposal--a so-called "best price" rebate plan--was based on a program the Merck Company had developed. The Merck model sought first and foremost to block a state formulary option and government price controls on drugs. On the other hand, it implied that rebates could reduce Medicaid's net drug expenditures while leaving in place the market price, EAC reimbursement system. In short, the plan offered a tradeoff: protection of firms from the economic restraints of government formularies in exchange for budget relief through rebates.⁴⁹

65. In the end congressional negotiations produced a complex legislative result. The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) was the formal

⁴⁸ In 1989, the members of the Senate Special Committee on Aging heard testimony by Gerald Mossinghoff, President of the Pharmaceutical Manufacturers' Association, indicating that "average wholesale price is not determined by our companies. It's determined in part by surveys done of our companies." ("Skyrocketing Prescription Drug Prices," Hearings before the Special Committee on Aging, U.S. Senate, 18 July 1989: 157). Members of Congress did not hear from PMA that AWP's would be raised to create the spreads designed to foster competitive advantage. There is irony in this omission. On the one hand, there is the longstanding PMA position against government "price-setting" and in favor of competition, which in theory would hold prices down. On the other hand is the reality that the competitive strategies employed by some PMA members over time to gain market share led to the increasing prices borne by public payers.

⁴⁹ For evidence of the extent to which the Merck program and eventual OBRA 1990 deal were seen as a trade of rebates for open formularies, see "Merck is Offering to Cut Drug Costs of Medicaid Uses," New York Times, 21 April 1990; "PMA Board Approves Medicaid Rebate Plan", PMA Newsletter, 1 October, 1990 and "Medicaid Best-Price Drug Plan Written into Budget Summit Agreement", PMA Newsletter, 8 October, 1990.

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legislative product, of which the drug payment policy changes were but one part. OBRA 90 was essentially a bargain: side payments (rebates) by manufacturers to state and federal governments on all drugs if states give up the use of formularies as cost control instruments. Rebates were--and are--proportional payments paid on the basis of a reported “best price” or average manufacturing price (AMP). AMP and “best price” were to be confidential prices reported by drug companies only to the HCFA/CMS Office with responsibility for administration of rebates.⁵⁰ State governments did not have access to these prices.⁵¹ In short, whether drug firms reported AWP or WAC accurately did not make any fiscal difference to what was owed in rebates. This understanding of rebates illustrated the degree to which the OBRA legislation was about high drug prices and governmental budgetary relief⁵² rather than the price reporting practices of drug firms or reform of drug reimbursement policy.

66. The impact of this bargain, however, differed substantially from what reformers expected. Some firms in the industry quickly raised their “best prices.”⁵³ Drug firms invented new product forms to get around OBRA prohibitions against inflation in established products.⁵⁴ The scale of this policy failure to contain drug inflation is

⁵⁰ OBRA 90 defined the original rebate formulas. For single source and innovator-generic drugs, the rebate is the greater of 15.1 percent of the AMP or the full difference between the AMP and best price available in the market place. Rebates for generic drugs were initially a flat 10 percent of the AMP, and increased to 11 percent after 1993.

⁵¹ Manufacturers are supposed to pay states a Unit Rebate Amount (URA) for each of their drugs based on the application of the appropriate formula.

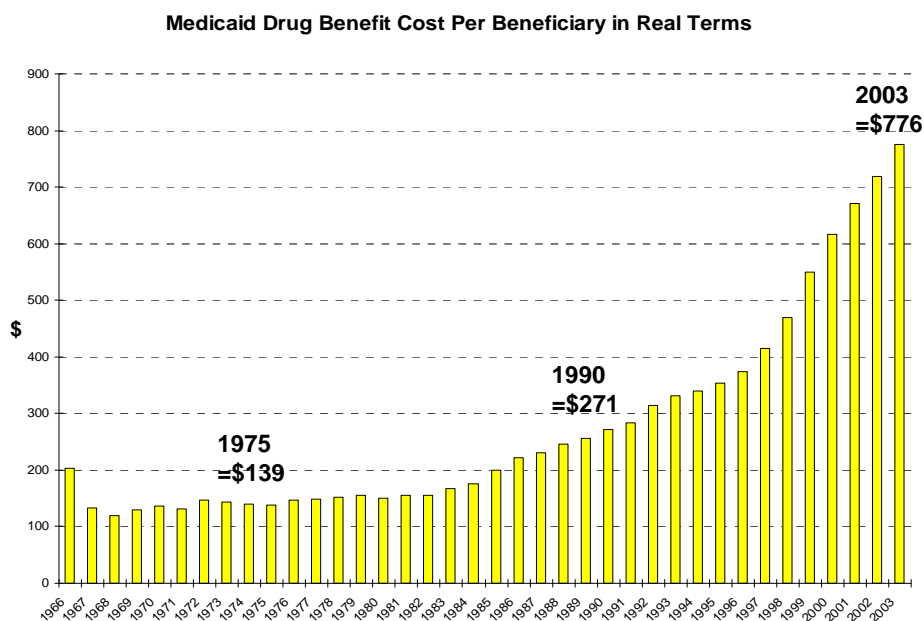
⁵² Pear, Robert, “The Struggle in Congress; Most in US Will Feel Effect of Shift in Spending Priorities,” New York Times, 28 October 1990.

⁵³ Consider a NY Times report: “But a lobbyist for the drug industry, who would speak only on the condition of anonymity, said ‘We are surprised that Senator Pryor is surprised. I don’t know what else he would have expected. It’s logical that companies would re-examine their prices if Congress passes a law saying that Medicaid, which accounts for 10 percent of our revenues, must get the best price given to any pharmaceutical customer in the country.’” (Pear, Robert, “Medicaid is Denied Discounted Drugs Despite a New Law,” New York Times 18 February 1991).

⁵⁴ Scott-Morton, Fiona, Duggan, Mark, The Effect of Medicaid Regulations on Drug Product Introductions and Pharmaceutical Prices, 5 April 2004, at pg. 2 (Introduction) & pg. 2 (Conclusions).

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noteworthy. In the decade from 1990 to 2000, Medicaid drug spending jumped from \$5 to \$20 billion, and increased almost threefold on an inflation-adjusted per beneficiary basis. One effect of the high rate of drug inflation was a sharp increase in the number of reports in the late 1990's by the Office of the Inspector General in HHS. This is outlined in appendix 3.⁵⁵



Sources: Yearly data - 1966 Comptroller General Memo; 1967-1974 US House of Representatives Report; 1975-1989 HCFA Medicaid Source Book; 1990-1998 HCFA 2082 Reports; 1999-2003 MSIS Reports; Data converted from nominal to real 2003 dollars using the bureau of labor statistics conversion calculator.

ii. The False Claims Story: How a Whistleblower Campaign Contributed to Congressional Demands for Policy Change in Drug Reimbursement

67. In the 1990s, the officials of a home infusion provider, VAC, conducted a campaign to reveal what they regarded as fraudulent conduct in price reporting by manufacturers for use by Medicare and Medicaid.⁵⁶ VAC--assisted by lawyers operating

⁵⁵ The OIG reports over this period focused on the gap between estimated and actual drug acquisition costs. Eleven OIG reports in 1996-97 focused on Medicaid's drug payment experience in a sample of states. Two others in 1997 and 2001 focused on similar issues in Medicare outpatient drug reimbursement.

⁵⁶ VAC was a home infusion provider in Florida that brought a qui tam suit against National Medical Care (NMC) in the early 1990s. Their principal officers alleged violations under the Stark anti-fraud statute.

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under the provisions of the False Claims Act--reported their understanding of the marketing practices and actual drug prices of certain drug manufacturers to a wide variety of federal and state officials. They made extended presentations to state attorneys general, officials at HCFA, the HHS OIG, state Medicaid Fraud Control Units, the US DOJ and Congressional investigators. (See Appendix 2 for a chronology of their efforts.) They emphasized the creation and marketing by some drug firms of very large spreads between acquisition costs and published prices for Medicare and Medicaid drugs.

68. VAC's presentations would become a major stimulus to congressional scrutiny of the pharmaceutical industry's pricing practices. Without their participation, the course of drug reimbursement policy might well have been very different. The campaign had these highlights. Between the initial allegations in the early 1990s and the more public testimony in 2001, VAC officials and their lawyers made a large number of presentations, adjusting length and focus to make their claims more understandable and to prompt, through revelations of what they regarded as blameworthy, changes in drug company reporting practices and marketing behavior. Over that decade, they were largely successful in transforming governmental understanding from what had been disputes about the extent of the gap between reported and actual acquisition prices into comprehension of outrageous and deliberate misrepresentation of drug transaction prices to Medicaid and Medicare and its fiscal intermediaries.

69. A revealing illustration of their influence was the conversion of leading congressional actors to their point of view. The Commerce Committee began its

Eight years later, in 2000, NMC (by then a unit of Fresenius) settled with the United States for \$486M. At that time, the settlement was "the largest case of its kind." (Steinhauer, Jennifer, "Justice Dept. Finds Success Chasing Health Care Fraud," New York Times 23 January 2001).

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investigation of Medicare drug payments in 1999.⁵⁷ Within a year Committee Chairman Congressman Thomas Bliley (R-VA) was sufficiently concerned about VAC's representations to share information on his findings through sharply worded letters to Clinton Administration officials.⁵⁸ These emphasized the "setting and marketing of the spread" and worrisome "impact of the spread on utilization decisions." Bliley transmitted similar sentiments to pharmaceutical companies.⁵⁹ (It is noteworthy that Democratic Congressman, F. Pete Stark--the most experienced health policy figure on the House Ways and Means Committee--also wrote a letter with similar charges to the CEO of Abbott, which was one of the firms under investigation by Congress).⁶⁰ The process of converting congressional actors into agents of policy change was, with bipartisan support, well on its way.

70. The story became more publicly prominent in September of 2001 at a congressional hearing entitled "Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers." There was testimony by representatives of the GAO, HHS OIG,

⁵⁷ VAC officials were subpoenaed and then questioned privately by committee investigators in September, 2000. A press conference and document release followed. See "Deposition of Zachary Bentley," United States District Court, District of Massachusetts, In Re: Pharmaceutical Industry Average Wholesale Price Litigation, 15 May 2007: 141.

USA Today reported on the growing concern of congressional investigators, and noted that "some of the documents...come from a whistleblower, Ven-A-Care pharmacy." (Appleby, Julie, "Drugmakers Accused of 'Unethical' Pricing," USA Today, 27 September 2000).

⁵⁸ Representative Tom Bliley Personal Communication to HCFA Administrator Nancy-Ann Min DeParle, 25 September 2000 PHRMA_AWP 020179. The Congressman reports at page 5: "a review of utilization patterns strongly suggests the use of vancomycin, the antibiotic of last resort in treating otherwise deadly bacterial infections, may have dramatically increased as a result of the excessive Medicare spreads effectively created by Abbott Laboratories. Many experts believe that, as a result of such types of over-utilization, new vancomycin-resistant bacteria recently have emerged as a growing public health risk."

⁵⁹ Representative Tom Bliley Personal Communication to Dey Pharmaceuticals, 4 May 2000 PHRMA_AWP 020214. The Congressman argues on page 2, "I would find it hard to believe that when AWP was adopted as the benchmark for Medicare reimbursements, Congress intended to allow drug manufacturers to charge Medicare whatever they wanted, or permit the use of Medicare dollars to incentivize the use of particular drugs or increase sales or market share...it is imperative that those who provide these services insure that prices being paid by Medicare reflect actual market-based prices, consistent with the intent of Federal Law."

⁶⁰ See Congressman Stark's letter to Abbott CEO Miles White, 31 October 2000 (ABT-DOJ 0187889-95).

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trade associations, CMS Administrator Tom Scully and VAC Chief Executive Officer Zachary Bentley. The hearing was, according to members of the committee, the “culmination of years of investigation and audit work performed by the subcommittee staff and members of the first panel.”⁶¹

71. The claims VAC made were summarized by Mr. Bentley. “It became apparent to us,” he asserted, “that many drug manufacturers reported truthful prices, while others falsely inflated their price reports so that their targeted customers--oncologists, urologists, home care companies, ESRD providers, DME companies, and others--would be induced by the resulting windfall profits to order their drugs.”⁶² The public record of the hearing contained dozens of industry documents received from VAC that illustrated price manipulation and undeniable marketing of “the spread.”

72. At the hearing juncture, CMS Administrator Scully agreed with this critical diagnosis. He discussed the regulatory history of Medicare payment policy and concluded that a legislative solution to the problem was necessary. He suggested average manufacturer price and average sales price as possible remedies. In his written testimony, Mr. Scully ⁶³ accepted that “by offering physicians and providers deep discounts compared to the price they could bill Medicare, the drug manufacturers are able to use the profit margins to manipulate physicians and providers to use their products for Medicare beneficiaries.”⁶⁴

⁶¹ “Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers,” Joint Hearing before the Subcommittee on Health and the Subcommittee on Oversight and Investigations, 21 September 2001.

⁶² *Ibid* at pg. 48.

⁶³ Scully’s views as Medicare’s administrator were in sharp contrast to his behavior as a lobbyist in the 1990s. In that role he had pressed for the continuation of the AWP basis of reimbursement, knowing at the earlier time the gap between prices reported and paid. Deposition of Thomas A. Scully, 15 May 2007: 266-267.

⁶⁴ “Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers,” Joint Hearing before the Subcommittee on Health and Subcommittee on Oversight and Investigations, 21 September 2001: 88.

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73. VAC's revelations provided congressional officials with a clearer understanding of the realities of drug firm pricing practices than they had previously. The VAC campaign was not, it is plain from the historical record, the only reform development in this period. The DOJ initiated its own investigation, understandably unwilling to accept allegations from others as the sole basis for intervention. That would not only take time, but also provide a different channel of governmental action from the mid-1990s on. Moreover, the DOJ investigation separated HCFA leaders' concerns about the gaps between actual and estimated drug acquisition costs from the broader charges at issue for the DOJ.⁶⁵ Accordingly, the report now turns to a brief review of the policy disputes and developments in the Medicare channel.

iii. Medicare, Drug Inflation, and Developments in the 1990s

74. As noted earlier, Medicare had from the outset faced serious budgetary problems from continuing inflation in medical prices and consequent increases in program expenditures. The role of drugs in that inflationary development would, in the 1990s, become a more substantial object of concern. The processes by which Medicare came to different policies towards drug reimbursement after 2003 are complicated, requiring attention to what might seem like unrelated developments. That requires identifying first how the program dealt with inflationary forces in the major components of expenditure: physician payment and hospital financing.

⁶⁵ HCFA Administrator Bruce Vladeck "was advised that these issues (the VAC claims) were under investigation." (Deposition of Bruce C. Vladeck, 21 June 2007: 488). His successor, Nancy-Ann DeParle, stated "it was my understanding that the Justice Department officials were involved in investigating those claims." (Deposition of Nancy-Ann DeParle, 18 May 2007: 234-5). Both Vladeck and DeParle treated the question of fraud investigation as a DOJ responsibility. This is precisely what Model II analysis would anticipate.

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75. Note that between 1975 and 1987, Medicare's spending per enrollee for physician services had grown at an average annual rate of 15%, almost twice as fast as the per-capita gross national product.⁶⁶ That, in turn, prompted legislative reaction, just as earlier in the decade, the Congress had agreed to large changes in how Medicare paid for hospital services under Part A.⁶⁷ In 1986, the Congress had created the Physician Payment Review Commission (PPRC) to provide advice on ways to reform Medicare's method of paying physicians.

76. By December 1989, the Congress, acting on the advice of PPRC, mandated that Medicare's physician payment methodology be revised by HCFA. In place of the previous charge-based reimbursement methodology, payment levels were to be determined on the basis of the relative resources--including physician work effort, practice and malpractice expenses--required to perform services. The development and implementation of this "resource-based relative value scale system" (RBRVS), would, it was widely hoped, slow the growth in Part B spending for physician services.

77. Though Part B drugs were excluded from the RBRVS process, they did not escape consideration in the overhaul. The Bush Administration, for instance, proposed to pay 85% of AWP,⁶⁸ citing OIG reports that suggested AWP payments were approximately 15% greater than actual acquisition costs for some drugs.⁶⁹ The final rule

⁶⁶ "Medicare Physician Payment: Geographic Adjusters Appropriate but could be Improved with New Data," GAO July 1993: 3.

⁶⁷ See Oberlander: 123-24.

⁶⁸ "Medicare Program: Fee Schedule for Physicians's Services (Proposed Rules)," Federal Register, 5 June 1991: 25800-01.

⁶⁹ In a discovery document in this case, an Abbott official noted the proposed change to 85% of AWP reimbursement and warned in an internal memorandum that the "framework for a downward spiral of drug prices is laid through these rules." He notes that the ASCO, PMA, American Society of Nephrology (ASN), and Alliance for Infusion Therapy "have vested interests in resisting these changes" and will be "contacted by appropriate Alternate Site and Abbott Washington personnel to determine a response to the proposed rules changes." (ABT212056 – 14 June 1991). Another memo from Abbott's Manager of

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adopted, however, was for the “lower of national AWP or the Medicare carrier’s estimate of actual acquisition costs.”⁷⁰ EAC was to be determined by HCFA surveys. In deciding the standard, Bush officials again cited the complaints of physicians who suggested “many drugs could be purchased at less than 85% of AWP – particularly multi-source drugs – while others were not discounted.”⁷¹

78. The RBRVS regulations became effective January 1, 1992.⁷² From 1992 until the Balanced Budget Act of 1997, the reimbursement policy for Part B drugs remained the same. The scant historical information available suggests that OMB blocked HCFA from using the survey instrument developed due to paperwork concerns.⁷³ AWP became the de facto payment mechanism.

79. With the election of a Republican Congress in 1994, the debate over spending-control and budget-balancing became more vociferous. In health care policy, some commentators, including the GAO, claimed that 10% of Medicare spending was the result of “waste, fraud, and abuse.” In August, 1996, Congress passed The Health Insurance Portability and Accountability Act (HIPAA), one provision of which allowed funds recovered from government healthcare fraud litigation to be invested back into government litigation efforts. Qui Tam cases multiplied in the decade that followed, as

Reimbursement is an examination of strategies for response to the NPRM; the first offered was that “discounts vary among purchasers. Some providers may pay full A.W.P. and others may get a discount but not a full 15% due to manufacturer discounting practices.” (ABT212051, 11 June 1991). This level of discussion concentrated on what, by comparison to the spreads uncovered by the Ven-A-Care campaign, were relatively restricted, if still consequential in impact on total expenditures.

⁷⁰ “Medicare Program: Fee Schedule for Physicians’s Services (Final Rules)” Federal Register 25 November 1991: 59507.

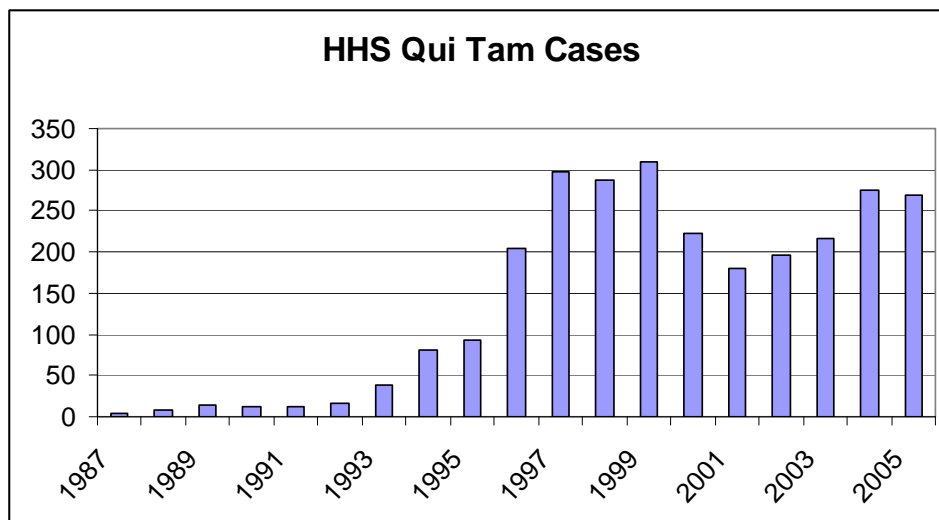
⁷¹ Ibid at 59524.

⁷² The practice and malpractice expense components of physician reimbursement continued to be paid on the basis of historical charges and were not scheduled to be rolled into the RBRVS methodology until 1999, when they would be implemented over three years. This plan was ultimately delayed by BIPA 1999.

⁷³ See Deposition of Bruce Vladeck, 21 June 2007: 384-88.

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did settlement totals.⁷⁴ All of these developments were part of a separate – i.e. legal -- channel of governmental behavior.



80. For Medicare in 1998, President Clinton proposed actual acquisition costs as the basis for reimbursement of Part B drugs. And, after months of consideration, Congress instead substituted a 95% of AWP basis in the final legislation that contained over 300 Medicare provisions. The pharmaceutical industry, either through its industry association, The Pharmaceutical Research and Manufacturers Association (PhRMA), or its members directly,⁷⁵ spent some \$50 million in lobbying in 1996 and 1997 during the lead-up to passage of this legislation, the BBA.⁷⁶

⁷⁴ “Information on False Claims Act Litigation” GAO-06-320R 15 December 2005: 26. Recoveries grew as well; The New York Times reported that “from 1997 to 2000, recovery in civil fraud cases grew by more than 50%, and last year, of the \$1.5B recovered by the federal government from fraud cases generally, \$840M was from those involving healthcare.” (Steinhauer, Jennifer, “Justice Dept. Finds Success Chasing Health Care Fraud,” New York Times, 23 January 2001).

⁷⁵ Abbott itself expended on the order of \$15 million on lobbying between 1996 and 2000. (“Prescription for Power,” Common Cause, June 2001). Discovery documents in this case demonstrate the aggressive nature and sophistication of their efforts in trying to influence the course of Medicare Part B drug reimbursement policy, particularly during the BBA consideration. Abbott’s Washington Office tracked President Clinton’s AAC legislative proposal and noted “an industry meeting to discuss strategy with regard to this issue has been tentatively scheduled for...February 20.” (ABT-DOJ 296012, 10 February 1997). Coordination with other interest groups--the American Society of Clinical Oncologists (ASCO) and “the renal community”--allied against the AAC proposal is apparent. (ABT-DOJ 296152-4, 4 April 1997) Senate and House Committee deliberations were followed by the office and a “well known health

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81. The Clinton Administration would propose similar reductions in reimbursement levels for Part B drugs with their budget submissions in 1998, 1999, and 2000. (In December, 1997, President Clinton expressed his FY98 budget proposal for payment at actual acquisition costs to the country during a radio address⁷⁷). These efforts were met by strenuous lobbying from provider and patient groups in the form of allegations of underpayment for practice expenses associated with Part B (“incident-to”)

lobbyist.” (ABT-DOJ 296142, 16 May 1997). A major law firm, Hogan and Hartson, employing former members of Congress and previous Administration officials, drafted “amendments to the President’s budget bill.” (ABT-DOJ 296144, 16 May 1997). Abbott officials “met with members of Congress and staff on the issue of Medicare drug reimbursement being changed from average wholesale price to acquisition cost.” (ABT-DOJ 295983, 5 June 1997). Abbott officials noted favorable policy language -- 95% of AWP-- in the House bill, but identified troubles with the Senate bill (which granted the Secretary discretion to set payment levels below 95% of AWP) and suggested revisions to legislative language. (ABT-DOJ 296018, 13 June 1997). Attention was given to the composition of the House-Senate conference committee. There were references to likely conferees Congressmen Bill Archer and Dennis Hastert, whose districts had Abbott plants or offices and might be targeted for letter-writing campaigns. (ABT-DOJ 295994, 20 June 1997). The Washington office enlisted Abbott CEO Duane Burnham in the effort to win passage of the House bill. A divisional VP wrote that “Abbott has a lot at stake in this reimbursement fight. I do not want to feel, or having (sic) others feel, that we did not do everything possible to win in conference.” (ABT-DOJ 295994, 20 June 1997). A phone call between Abbott Chairman Burnham and House Ways and Means Committee Chairman Archer took place prior to final passage of 95% of AWP policy; Abbott CEO wrote a letter of thanks to Chairman Archer afterwards noting “when we spoke on the phone you said you intended to hold the House language in conference committee and you did...Abbott thanks you for convincing the rest of the conferees.” (ABT-DOJ 296003, 5 August 1997).

This episode--and the Model III data on which it is based--does not illustrate government acquiescence and approval in Abbott’s price reporting conduct, which was not fully disclosed and had not been the basis of the lobbying. Rather, it exemplifies the difficulty of reforming a model of reimbursement with which interested parties have become familiar. It also illustrated the capacity of Abbott and other firms to protect a system of reimbursement in which the government had to rely upon the reported prices of drug firms. (From another discovery document in this case, we know that the broader industry association lobbied against the 1997 AAC proposal: “PhRMA expressed support for a proposal to reimburse at AWP.” See PHRMA_AWP 007929).

⁷⁶ “Prescription for Power,” Common Cause, June 2001. No one can claim that lobbying is illegal; it is of course part of the American political world, accepted as defending one’s interests before governmental authority. Such lobbying helped to defeat President Clinton’s AAC plan. But, to see in the adoption of the 95% AWP policy government acquiescence is incorrect. Abbott officials did not lobby for a system of vastly inflated price reports. They lobbied against a reduction in reimbursement that would not cover provider cost, and against a system that would have required them to report actual acquisition costs.

⁷⁷ “Remarks by the President in Radio Address to the Nation” White House Office of the Secretary, 13 December 1997.

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drugs.⁷⁸ Each time the Clinton proposals were rebuffed by the Republican Congress and the 95% of AWP payment stayed in place.

82. During this period, Congress ordered three studies of payment policy implementation and related matters.⁷⁹ The impact of these studies is somewhat paradoxical. On the one hand, the studies were part of the campaign to transform AWP reimbursement. On the other hand, studying a topic necessarily produces delay in the reform of a policy. To illustrate, consider the 2000 legislation, The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA).⁸⁰ That statute required the GAO to assess whether physicians were adequately compensated for Part B drugs and related expenses.⁸¹ This fact-finding is typical of a reform process. Yet, during the course of the study, the Congress called for a moratorium on changes in reimbursement

⁷⁸ In the discovery documents for this case, I saw numerous examples of this sort of lobbying. One letter (17 December 1997) from the American Society of Clinical Oncologists to members in response to the Clinton radio address claimed having checked with Congressman Archer, who as Chairman of the House Ways and Means Committee was pivotal in killing the Administration proposal, and he strongly supports not changing the drug reimbursement mechanism that was enacted this year." A sample letter about how to lobby elected officials was included.

⁷⁹ For instance, in 1997, the BBA contained a requirement for the HHS Secretary to study the effects of the 95% of AWP policy and report to Congress by 7/1/99. ("Balanced Budget Act of 1997" PL 105-33 5 August 1997). The HHS report found mixed evidence on the question of AWP rate growth acceleration generally. A Chicago Tribune report obtained from discovery in this case notes that Abbott raised the AWP for one drug, Lupron, by 10% from 1998 to 1999, "offacting (sic) the lower government allowance." This was precisely the concern some in the Congress had in mind when ordering the study. (Zujac, Andrew and Cohen, Laurie, "Feds Probe Abbott Venture's Drug Sales," Chicago Tribune 23 May 1999).

A second instance was in 1999, when Congress passed the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act (BBRA). ("Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999" PL 106-113 29 November 1999). There, one provision required the GAO to study the "adequacy of Medicare payments to oncologists" under the recently implemented RBRVS overhaul for administrative expenses.

⁸⁰ "Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000" PL 106-554, 21 December 2000.

⁸¹ The GAO concluded that physicians were able to obtain "incident-to" drugs at prices well below AWP. "For most physician administered drugs, the average discount from AWP ranged from 13 to 34%. Two physician administered drugs had discounts of 65% and 86%." ("Payments for Covered Outpatient Drugs Exceed Providers' Cost" GAO, September, 2001: 4). Oncologist administrative costs--reimbursed by the practice expense RBRVS component rolled out in 1999--were 8% higher than with the old charge-based system. Another component--practice expenses associated with non-physician care--was found to be somewhat underpaid.

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methodology.⁸² One might imagine a moratorium as a victory for the status quo. In this instance, that interpretation does not apply. Indeed, the delay had the support of one of the most serious critics of the behavior of the pharmaceutical industry in drug pricing, Congressman Stark of California. Context, in short, shapes meaning.⁸³

83. The 2000 legislation--and its aftermath--reflected the confluence of the three channels I have described. Drug pricing revelations became more public and more contested. For example, the National Association of Medicaid Fraud Control Units (NAMFCU) escalated the attack on the reliability of drug prices reported by First Data Bank. According to NAMFCU, the transaction prices were much lower than published AWP.⁸⁴ In September, 2000, HCFA sent its Medicare carriers the list along with qualifications for their usage.⁸⁵ The provider community appealed to Congress against usage of the prices. By November, HCFA sent a memorandum to carriers instructing them not to use the prices⁸⁶ and Congress ordered the BIPA study.⁸⁷ This combination of revelation, reaction, hesitancy, and further study is typical of controversial reform politics

⁸² "Medicare, Medicaid and SCHIP Benefits Improvement Act of 2000" PL 106-554, 21 December 2000, Sec. 429.

⁸³ DeParle tried to use DOJ AWP for certain part B drugs. Congress in an interim bill, labeled as a Medicare Anti-Fraud Bill relieved HCFA of the statutory obligation to use AWP, however. (This occurred after Bliley's letters to HCFA following his initial investigation). It required, with Stark's approval, that HCFA take no such action until the completion of a GAO study also required by the bill. The presentation of the GAO study occurred at the 9/21/01 hearings at which substantial additional information was provided to the Congress as detailed above.

⁸⁴ These prices had been collected from a federal/state investigation originating from the VAC qui tam allegations. (NAMFCU Letters from 16 February 2000 and 18 May 2000).

⁸⁵ "An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program" CMS Program Memorandum, 8 September 2000.

⁸⁶ An internal Abbott memorandum described the HCFA retraction of investigation AWP as "good news," but "not good news that Congress continues to have an interest in this issue." The House passage of the provision requiring GAO study and likelihood of future hearings are noted. Congressman Bliley--"the lead antagonist on this issue"--is retiring; likely successors are seen as "friends of Abbott and not likely to take the same combative approach on the issue as Mr. Bliley." Haas, Rosemary, "AWP: HCFA Reverses on Implementation of Drug Payment Reduction" e-mail to Abbott Co-Workers, 22 November 2000. (ABT-DOJ 0236630).

⁸⁷ "An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program" CMS Program Memorandum, 17 November 2000.

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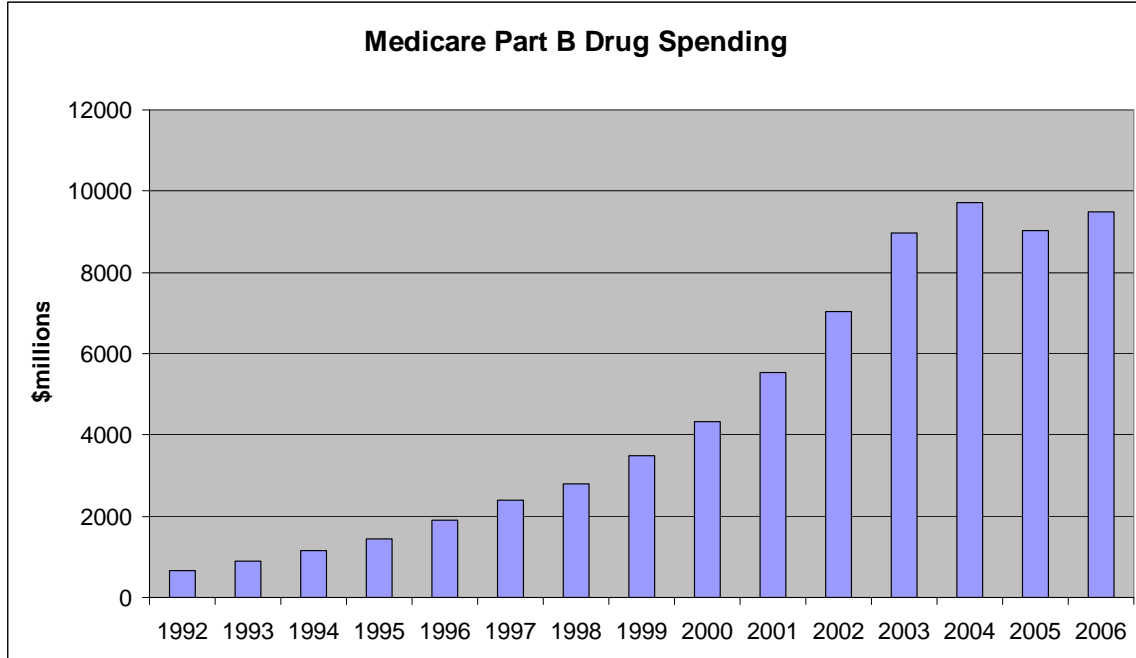
in America. Interpretation is not simple. Knowing the balance of influences that generated this sequence is itself a substantial research task. But, what can be claimed with confidence is that the bargaining over a substantial change in drug reimbursement policy was in this period begun in earnest.

84. The 2000-01 investigations were an important element in a decade long story. They helped shift the position of influential congressional Republicans. That in turn made more probable the reforms introduced later by the Medicare Modernization Act of 2003.⁸⁸ The implementation in 2005 of a new Average Sales Price standard for reimbursement, for instance, would replace the AWP basis for most Part B drug reimbursement.⁸⁹ During the period of this case, Medicare Part B drug spending grew dramatically in real terms and as a percentage of Part B spending over the decade. Only the MMA implementation would level off that steep growth curve.

⁸⁸ “Medicare Prescription Drug, Improvement and Modernization Act of 2003” PL 108-173 8 December 2003.

⁸⁹ “Medicare Prescription Drug, Improvement and Modernization Act of 2003,” PL 108-173, 8 December 2003, sec 301-2239.

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Source: CMS Office of the Actuary

iv. Other Developments in California

85. As I understand it, this case concerns the time period from 1994 to 2004. The longer, more general history described above is, of course, relevant to the story of California's drug pricing. However, I also have reviewed and considered additional historical data specific to California's experience with drug pricing and reimbursement in reaching my conclusions in this case. Far from demonstrating approval, or even acquiescence, in the pricing conduct of the defendants, the historical record shows California's repeated efforts to restrain its drug spending, as well as the pharmaceutical industry's sustained lobbying and other activities to thwart such efforts.

86. In 1989, under pressure from HCFA to discount (as was the case more generally in this period), California started a full-scale regulatory process that resulted in implementation of an AWP-5% standard (from an undiscounted AWP, the typical earlier

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state mode), a \$4.05 dispensing fee, and direct price contracts with 12 drug firms. The DP contracts were designed to lower reimbursement for the relevant products.

87. Even before the federal government established Medicaid rebates through OBRA 90, California had established its own state rebate program by 1990. This program originally applied only to brand drugs, unlike OBRA federal rebates that applied to both brand and generic drugs. However, from 1994-96, there was a one-time legislatively imposed mandatory supplemental rebate that applied to all drugs and manufacturers, the extension of which was vigorously resisted by the drug industry. The supplemental rebate program presently continues in effect for branded drugs. Generic manufacturers have generally refused to enter into supplemental rebate agreements with California. (I note that defendant Sandoz briefly had a supplemental rebate contract for one of the Sandoz's generic drugs, a drug for which California has brought suit.). Since branded drugs continue to account for approximately 80% of Medi-Cal's total drug expenditures, (which are approaching \$6 billion per year in an overall \$40 billion program), California health officials have been understandably more preoccupied with branded drug costs and total Medi-Cal expenditures than on generic drug costs.

88. In 1994-95, California was in the throes of a state fiscal crisis. Without study, the legislature reduced the reimbursement for each drug claim by 50 cents, a figure later reduced to 25 cents, and then 10 cents. The legislature tried to take other steps at this time, but none other than the claim reimbursement reductions and the supplemental rebate contracts described in the previous paragraph were enacted. The historical record shows that these were efforts to reduce public expenditures, not efforts to reform the drug reimbursement system nor deal with possible fraud.

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89. In 1996, OIG reports identified the increasing spreads in California drug prices, particularly in generics. Medi-Cal prepared proposals for the California legislature to increase the discount (towards 10%), but these proposals did not make it out of the legislature. Instead, in 1999, the California legislature instructed Medi-Cal to commission a study so that some agreement could be reached about what action to take. That study would be performed by the Myers&Stauffer firm and was completed in 2002.

90. The legislature was in stalemate for much of the period 1996-2002. In 2002, the legislature decided that drug reimbursement would be decreased to AWP-10%, eliminated direct price payments (DP) as a standard, and kept the same dispensing fee. It is my understanding that the defendants claim that this modest decrease in some way supports their claims of approval or acquiescence. I disagree. There were continuing battles, both political and legal, during this period. *See, e.g., Orthopaedic Hospital v. Belshe*, 103 F.3d 1491 (9th Cir. 1997) (describes lengthy litigation over reimbursement rates in California). Efforts to make change that were thwarted by lobbying and litigation—or slowed by independent study-- hardly qualify as evidence of approval or acquiescence in the pharmaceutical companies' conduct.

91. By 2002, the indicators of increasing spreads between reported and acquisition costs prompted the legislature to enact an increased discount from AWP-5% to AWP-10%. Shortly after the 2002 changes were implemented, Myers&Stauffer issued its report. The report distinguished between acquisition costs and dispensing fees. In response, in 2004, the legislature made a more substantial change to AWP -17%. That change was part of an overall adjustment of policy. There was an increase in dispensing fees: from \$4.05 to \$7.25 (for pharmacies) and \$8 (for long term care facilities).

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92. During the relevant time period and at the federal level, the pharmaceutical companies resisted any changes to the AWP method--or alternative measures--through vigorous and costly lobbying. In California, there were other forms of resistance to increases in AWP discounting or alternative methods of reimbursement. In Dey's case, a lawsuit was filed, which sought to enjoin First Data Bank from reporting much lower and apparently more accurate prices. *See* Complaint in *Dey v. First Data Bank, Inc.*, Superior Court of the State of California (Napa County), Case No. 26-21019 (April 15, 2003). The arguments defendants give now for why changes were not made are, first, the notion that the "government" acquiesced in what "everyone knew" were inflated "list" prices. Second, the defendants and some of the experts they have hired contend that prices were inflated in order to ensure access to drugs (the so-called "cross-subsidization" point).

93. The historical record does not support the defendants' contentions. No one agreed to the level of inflated prices that were used. Nor did the drug companies come clean at all about that level of inflation. Moreover, on the cross-subsidization claim, the dispensing fee remained flat for some time and, when it changed in 2004, it had to do with a large change overall. That sequence does not support the cross-subsidy claim. It does take into account the political power of pharmacies to push, when there is a big policy change overall, for some compensation to take into account their losses in revenue on the ingredient side. The fact that there was not a pattern of that adjustment over time, but only one big example in 2004, demonstrates the separate calculation that the policy calls for. The California government was more concerned with the overall

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budget impact and, as noted above and in the depositions of California officials, paid special attention to the net drug costs to the state.

94. Finally, the depositions of California officials that I have reviewed establish that they were unaware of the level of price inflation or of the manner in which the defendants marketed the spread until the present suit was filed and independent investigation by the State supported the allegations. This is not surprising given the conduct of the defendants and given the fact that the information previously available to Medi-Cal officials was almost entirely focused on averages, not on the conduct of specific drug firms and specific drugs. As is noted below, not all drug firms engaged in the sorts of machinations alleged against the defendants here, so reports addressing the industry as a whole in California could not have revealed the sorts of particularized misconduct alleged in this case.

IX. Additional Specific Response to Question Number 3.

94. With this overview of the policy history in mind, my conclusion is that neither the federal nor California governments approved of--or acquiesced in--the defendants' price reporting conduct as alleged in this case. I now will address the additional questions posed in section I.

How do the following facts and information bear on my opinions?

(i) Medi-Cal's continued use of published prices (AWPs, WACs and Direct Prices).

95. The continued use of reported AWP (or WAC or direct) prices has a relatively simple explanation, one that does not reflect governmental acquiescence or approval of the price reporting of the defendants.

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96. First, the federal Government--in its many different parts--did not arrive at an agreed upon alternative reimbursement policy that was practical operationally and acceptable to the Congress. As a result there was no federal insistence on an overall shift in the drug reimbursement policy arena. This was the case through the 1990s. After the revelations of the 2001 congressional hearings, the stage was in fact set for a change in Medicare's drug reimbursement policy in conjunction with a major transformation in that program's structure and drug coverage. Similarly, the history detailed above demonstrates years and years of debate about, as well as legal challenges to, pricing methodologies in California. Not being able to reach consensus about how to address pricing is not the same thing as approving of or acquiescing in behavior that was apparently designed to hide the facts and take advantage of the State's lack of information about the extent of the pharmaceutical companies' machinations (such as marketing the spread). Organizational analysis, as set out in the text of the report, is the main basis for this conclusion. In addition, the role of particular reformers--and actors in the Congress, the DOJ, and other institutions-- provides support for this conclusion.

97. The reasons for the continued use of published prices in California are largely the same. The history detailed above is one of years of struggling to get to appropriate pricing methodologies. California sought to contain prices using these methods, and achieved some success. First, California applied 5% discounting from AWP. Second, there was the 10% rebate program between 1994 and 1996, itself an important contributor to lower net costs of Medi-Cal's drug program. Third, there was the 1995 (effective) across-the-board reduction by fifty cents of each prescription, a reduction that itself was reduced over time. The shift from AWP minus 5% to AWP

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minus 10% in 2002 illustrates the response of California's policy makers, with a lag, to additional inflationary developments in the pharmaceutical industry. And, finally, following the report of the accounting firm Myers&Stauffer, California adopted an AWP minus 17% standard in 2004 and tried to implement a new MAIC program.

98. Moreover, throughout the period at issue in this case, providers and the drug industry used lobbying and litigation efforts to maintain the status quo, making it decidedly difficult for Medi-Cal or the state legislature to make changes in its methods. The history shows that California was mostly focusing on adjusting, not transforming, policy throughout this period – which is a much more common governmental activity and certainly helps explain the incremental adjustments described in paragraph 97.

99. It should be added that the honest presentation of prices--under AWP or WAC--was in fact an operational alternative that the drug industry could use properly--and some firms did. Finally, there is ample evidence that the continued use of AWP prices was the source of considerable public debate and extensive investigations by organizations of the federal and state governments, including California. The experiments with discounting, rebates and other examples testify to this. Nothing in this record supports the proposition that the government approved or acquiesced in the defendants' reporting of inflated prices.

(ii) The record of VAC's communications with various persons within the Federal Government (Congress, HHS, HCFA) and California.

100. As this report documents, VAC did indeed communicate with a considerable variety of governmental organizations and officials, including in California, and did so over a number of years. That is the basis for the report's characterization of

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VAC's "campaign" to impress upon governmental bodies the scale of misrepresentation in the reported prices used by Medicare and Medicaid. That the campaign was extensive in scope and time testifies to the difficulty in American politics of a) getting dispersed institutions to agree on both a problem and an acceptable remedy and b) convincing busy officials that this area of inflation (with others more obvious) should be the focus of reform effort. (One needs to recall that there were hundreds of Medicare and Medicaid-related qui tam suits in the 1990s. In that respect, these lawsuits were another channel of governmental reform action.)

101. There is nothing unusual about such a reform campaign--or the difficulty it faced--in convincing others that the problem of material misrepresentation was far beyond what was commonly assumed among those officials convinced that merely discounting from AWP was a workable option. This interpretation depends on understanding the conventions of legal process as compared to those of governmental policy-making. There were many steps between the campaign to draw attention to allegedly fraudulent conduct and the acquisition of the legally acceptable depth of evidence that the California Attorney General would require before taking action.

102. VAC's contribution to the California litigation was to persuade officials that the magnitude of the spreads was much greater than investigators previously had imagined. California's investigators buttressed their position with detailed information about particular drugs. VAC filed suit in 1998, but that suit remained under seal until 2003, when California's Attorney General intervened on behalf of the state. (Notably, this was the same year Dey filed suit in California to keep First DataBank from reporting more accurate prices.) In that five year period, there were numerous investigations and

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extensive research was performed before California opted to join the suit. VAC's actions were simply a prod to legal action, which makes sense and is entirely consistent with my opinions.

103. Indeed, the changes in California's drug reimbursement policy following VAC's revelations of fraud are also relevant. It provides additional evidence that the California's government agencies did not approve or acquiesce in the price reporting conduct at issue in this case.

(iii) Federal and California reports including those issued by the Office of the Inspector General (OIG), the California State Comptroller and studies by and for the California Medi-Cal program.

104. These reports, cited in the text above and listed in appendix 3, are part of the record of organizational units charged with exploring both fraudulent conduct and operational problems in the reimbursement and administration of public healthcare programs. The identification of differences between costs paid by providers and prices reported to the compendia was receiving increased attention and affirmed repeatedly by the OIG in the decade that followed. Likewise, the record shows a long history of California's efforts to grapple with drug reimbursement. It is notable that despite all of the efforts at the state and federal levels to understand and address drug pricing, none of the early reports revealed government knowledge of anything like the level of price reporting misconduct by drug firms that is alleged here. Rather, they reported *gaps* for some drugs between published prices and the prices available to some providers.

105. There was no consensus about the scope and scale of those gaps. And, until VAC's revelations, there was little or no understanding of the scale of the inflation or of the role played by manufacturers in causing inflated reimbursement. In short, clear

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and detailed understanding arrived much later. The more important point, however, is that Medi-Cal officials and Medicare fiscal intermediaries could not act boldly on reports of minor or major instances of inflated prices. They, as operational units, required a method of paying regularly for drugs that could be handled by computer programs. That is largely why reliance on discounting or rebates was more general in the 1990s, and understandable in the absence of documentation of extraordinary inflation of AWP prices by some firms and for some drugs.

106. These reports, coupled with the work of the California State Comptroller, helped identify problems with drug reimbursement in a general way at both the state and federal levels. None offered enough specificity to make it clear what remedies should be applied to these problems. Further, the studies and reports about drug pricing in California and at the federal level during this period show increasing incremental understanding of specific issues, but did not reveal the wholesale misconduct of the defendants in their pricing activities.

(iv) Federal and California (legal) investigations of drug pricing and reimbursements.

107. The same observation applies to this class of investigations by different institutions of American government. As this report emphasizes, American government is, in comparative terms, extraordinarily dispersed both functionally and geographically. No scholar of government would expect descriptions of “the American government’s” knowledge to be the basis for claims about what was known, what were thought to be options for change, and why action was or was not taken. Investigations by the United States Congress or by a state legislature like California’s serve a variety of purposes; there is no necessary connection between taking credit for identifying fraud and being

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able to get agreement on how to remedy the situation. This was particularly evident in the gap between the extraordinary hearings of 2001 and the changes of drug reimbursement in the Medicare Modernization Act of 2003 and beyond. The larger point is simply that investigative activities serve to place issues on the agenda of parts of the government; they do not bring with them the sufficient conditions of rapid remedial action. Nor do they reflect acquiescence or approval of the existing state of affairs. Investigations do play a crucial role in American politics. Without them, reform in the context of institutions sharing power and authority would be more unlikely.

108. As noted above, California took the time to investigate the allegations raised by VAC before acting. That investigation demonstrated sufficient misconduct to join the suit and pursue the defendants here.

Conclusion

109. Taken together, do these four features of the historical record challenge my opinions? The short answer is that the historical record does not undercut my opinion that neither the federal government nor California approved of or acquiesced in the price reporting practices at issue. This body of evidence--acknowledged and analyzed in my report--does not provide grounds for changing those opinions.

Theodore R. Marmor

Dated: June 30, 2009

Theodore R. Marmor, PhD

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Appendix 1: Government Anti-Fraud Program Chronology

1972 Passage of federal Anti-Kickback statute via SSA of 1972. Intended to protect federal health care programs and patients from fraud and abuse by limiting the influence of money on health care decisions. It prohibits payments in any form made purposefully to induce or reward the referral or generation of federal health care program business.

1976 The HEW Inspector General Act of 1976 (Public Law 94-505) creates the Office of the OIG. Two years later, a similar law is passed to create 14 additional inspector generals in other federal agencies.

1977 Congress strengthens anti-kickback provisions via Medicare-Medicaid Anti-fraud and Abuse Amendments.

1986 False Claims Act Amendments of 1986: "Congress made a number of changes in the False Claims Act, which dated to the Civil War. The original law, passed at the urging of President Lincoln to combat widespread fraud by suppliers to the Union Army, is still the Government's primary tool for prosecuting fraud. The new law provides that the Government may recover three times the amount of damages, up from double the amount. Civil penalties are increased from \$2,000 for each false claim under the old law to a maximum of \$10,000. In addition, the new law makes it clear that proof of intent to defraud the Government is not required in order for a defendant to be found guilty; proof that the defendant deliberately ignored or acted in reckless disregard of the truth will be sufficient." (NY Times 11/15/86)

1987 Congress again strengthens anti-kickback provisions via Medicare and Medicaid Patient and Program Protection Act

1989 OBRA 1989 – Stark I: prohibited physician self-referrals to clinical laboratories in Medicare. Effective in 1992.

1993 OBRA 1993 - Stark II: Added prohibitions against physician self-referral for other services and broadened to include Medicaid. Under the statute, criminal, civil, or administrative liability can result if one knowingly and willfully offers to pay for, solicit, or receive any remuneration to induce referrals of items or services reimbursable under federal health programs. Effective in 1995.

1995 GAO estimates that "fraud and abuse may account for 10% of healthcare costs." (GAO/T-HEHS-96-7) Senator Roth cites estimate in 2/14/96 hearing: "GAO has estimated that the loss from fraud and abuse equals approximately \$17B which is 10% of total Medicare spending."

1996 The Health Insurance Portability and Accountability Act of 1996, among other things, established a Health Care Fraud and Abuse Control Program (HCFAC) to strengthen ongoing efforts to combat fraud and abuse in health care programs. Under the HCFAC program, a portion of settlements and judgments resulting from FCA cases

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involving health care fraud are used to finance part of the antifraud activities in HHS and DOJ. In fiscal year 2004, HHS and DOJ were allocated over \$240 million from HCFAC program funds to devote to their health care fraud enforcement activities.

2006 GAO reports (GAO -06-320R) that the federal government has won recoveries of over \$15 billion from fiscal years 1987 through 2005. Of the \$15 billion, 64 percent, or \$9.6 billion, was for recoveries associated with cases filed by whistle blowers under FCA's qui tam provisions. Almost a third was for programs at HHS.

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Appendix 2: Ven-A-Care Chronology

10/94	VAC begins to contact state AG's
1995	VAC files lawsuit against various pharmaceutical companies, including Abbott
9/95	VAC meets with OIG and HCFA officials (pricing data to OIG follows)
10/2/96	VAC Letter to HCFA Administrator Vladeck
7/2/97	VAC meets with Texas Attorney General
3/19/98	VAC presentation to NAMFCU
3/20/98	VAC presentation to HCFA Administrator DeParle
12/7/98	VAC presentation to HCFA
1999	Commerce Committee investigation begins
9/00	VAC official (Z. Bentley) testifies privately to Commerce Committee; press conference and Committee release of documents leads to USA Today article
4/24/01	VAC presentation to Commerce Committee
9/21/01	VAC Testimony at public hearing of Commerce Committee

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Appendix 3: Related Government Reports (1980-2001)

	REPORT	SOURCE	DATE
1	Programs to Control Prescription Drug Costs under Medicaid and Medicare could be Strengthened	GAO	12/31/1980
2	Title XIX of the Social Security Act, Limitation on Payment or Reimbursement for Drugs	OIG	9/1/1984
3	Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in the Medicaid and Medicare Prescription Drug Program	OIG	10/3/1989
4	Changes in Drug Prices Paid by VA and DOD since Enactment of Rebate Provisions	GAO	9/1/1991
5	Physicians' Costs for Chemotherapy Drugs	OIG	11/6/1992
6	Changes in Drug Prices Paid by HMOs and Hospitals since Enactment of Rebate Provisions	GAO	1/1/1993
7	Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland, Fact Sheet for Congressional Committees, GAO/HRD-93-55FS	GAO	3/1/1993
8	Review of Management Controls Over the Medicaid Prescription Drug Rebate Program	OIG	6/1/1993
9	Medicare Physician Payment	GAO	7/1/1993
10	Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services	OIG	5/31/1996
11	Suppliers' Acquisition Costs for Albuterol Sulfate OEI-03-94-003932 (June 1996).	OIG	6/1/1996
12	A Comparison of Albuterol Sulfate Prices OEI-03-94-00392 (June 1996).	OIG	6/1/1996
13	Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Montana Department of Health Services	OIG	7/11/1996
14	Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Florida Department of Health Services	OIG	8/13/1996
15	Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the North Carolina Department of Health Services	OIG	9/4/1996
16	Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Delaware Department of Health Services	OIG	9/12/1996
17	Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Virginia Department of Health Services	OIG	11/21/1996
18	Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the New Jersey Department of Health Services	OIG	12/6/1996
19	Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Nebraska Department of Health Services	OIG	12/24/1996
20	Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Missouri Department of Health Services	OIG	1/21/1997
21	Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the District of Columbia Department of Health Services	OIG	1/31/1997
22	Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Maryland Department of Health Services	OIG	2/12/1997
23	Medicaid Pharmacy-Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs A-06-96-00030 (April 1996).	OIG	4/1/1997
24	Medicaid Pharmacy – Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs 1997	OIG	4/10/1997
25	Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products 1997	OIG	8/4/1997

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26	Excessive Medicare Payments for Prescription Drugs OEI-03-97-00290	OIG	12/1/1997
27	Audit of State Aids Drug Assistance Programs' Use of Drug Price Discounts A-01-97-01501 (January 1998).	OIG	1/1/1998
28	Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs A-06-97-00052 (May 1998)	OIG	5/1/1998
29	The Impact of High-Priced Generic Drugs on Medicare and Medicaid OEI-03-97-00510 (July 1998).	OIG	7/1/1998
30	Are Medicare Allowances for Albuterol Sulfate Reasonable? OEI-03-97-00292 (August 1998).	OIG	8/1/1998
31	Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs OEI-03-97-00293 (November 1998).	OIG	11/1/1998
32	Medicare Reimbursement of End Stage Renal Disease Drugs OEI-03-00-00020 (June 2000).	OIG	6/1/2000
33	Medicare Reimbursement of Albuterol OEI-03-00-00311 (June 2000).	OIG	6/1/2000
34	Aids Drug Assistance Program Cost Containment Strategies OEI-05-99-00610 (September 2000).	OIG	9/1/2000
35	Medicare Reimbursement of Prescription Drugs OEI-03-00-00310 (January 2001).	OIG	1/1/2001
36	Cost Containment of Medicaid HIV/AIDS Drug Expenditures OEI-05-99-00611 (July 2001).	OIG	7/1/2001
37	Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products 2001, A-06-00-00023	OIG	8/10/2001
38	Medicaid's Use of Revised Average Wholesale Prices OEI-03-01-00010	OIG	9/1/2001
39	Medicare Payments for Covered Outpatient Drugs Exceed Providers' Cost, Report to Congressional Committees, GAO-01-1118	GAO	9/21/2001

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THEODORE R. MARMOR

Yale School of Management
135 Prospect Street
P. O. Box 208200
New Haven, CT 06520-8200
Tel: (203) 432-3238 — Fax: (203) 432-3248
Email: theodore.marmor@yale.edu

EDUCATION:

Harvard University, PhD, 1966 (Politics and History)
Wadham College, Oxford, Graduate Research Fellow (Philosophy and Politics), 1961-62
Harvard College, BA, American History and Literature, 1960

EMPLOYMENT HISTORY:

1983-Present	Emeritus, Professor of Public Policy, School of Management, Professor, Department of Political Science, Yale University
2007	Adjunct Professor of Public Policy, John F. Kennedy School of Government, Harvard University
1999-Present	Adjunct Professor of Law, Yale University
1993-2003	Director of the Robert Wood Johnson Foundation's post-doctoral program in Health Policy, Institution for Social and Policy Studies, Yale University
1979-83	Chairman, Center for Health Studies, Institution for Social and Policy Studies, and Professor of Public Health and Political Science, Yale University
1976-79	Associate Professor, Committee on Public Policy Studies, University of Chicago
1974-79	Research Fellow, Center for Health Administration, University of Chicago
1973-79	Associate Professor, School of Social Service Administration, University of Chicago
1970-73	Associate Professor of Political Science and Public Policy, University of Minnesota and Associate Dean, School of Public Affairs, 1970-72
1967-70	Assistant and Associate Professor of Political Science, Member, Institute for Research on Poverty, University of Wisconsin
1966-67	Post-doctoral Fellow, University of Essex and Nuffield College, Oxford
1965-66	Instructor, Social Studies, Harvard University
1962-65	Teaching Fellow, Department of Government, Harvard University

PROFESSIONAL APPOINTMENTS

Fellow, Institute of Medicine, National Academy of Sciences, 1993-
Member of the Board, National Academy of Social Insurance, 1987-95, Fellow 1987-
Chairman of the Scientific Advisory Board of the Institut Pasteur/CNAM School of Public Health, 2007
Centennial Visiting Professor, London School of Economics, Spring term 2001-2003
Rock Carling Fellow, Nuffield Trust, England, 2001
Robert Wood Johnson Investigator Award in Health Policy Research, 2001
Visiting Fellow, Australian National University, 1999
Visiting Fellow, All Souls College, Oxford, England, 1998
Fellow, Netherlands Institute for Advanced Study, (NIAS), 1997-98
Visiting Professor, Kennedy School of Government, Harvard University, 1996; Spring, 2001
Visiting John J. Hill Professor at the University of Minnesota, 1996
Fellow, Canadian Institute for Advanced Research, 1987-1995
Visiting Fellow, Russell Sage Foundation, 1987-88
Flinn Foundation Distinguished Scholar in Health Care Management and Policy, Arizona State University, and University of Arizona, 1986

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“Rethinking National Health Insurance,” selected as best health article by Policy Studies Annual, 1977
 Research Fellow, Kennedy School of Government Institute of Politics, 1970
 Research Fellow, Adlai Stevenson Institute, 1969
 Kennedy School of Government Post-doctoral Fellowship (University of Essex and Nuffield College, Oxford) 1966-67
 Finalist, Allan Nevins Prize of the Society of American Historians, for PhD Thesis on “The Career of John Calhoun,” 1966
 Harvard Graduate School Fellowship, 1962-1965
 Rotary International Fellowship, 1961-1962
 Wadham College Essay Prize, 1962
 Woodrow Wilson Fellowship, 1961-1962
 History and Literature Prize, 1959
 John Harvard Prize, 1957, 1959
 Lockheed Leadership Scholarship, 1956-1960

SIGNIFICANT GRANTS:

Principal Investigator, “Political Analysis: Applications to Health Care and Health Policy,” funded by the Robert Wood Johnson Foundation, 2001-2003
 Director, Robert Wood Johnson Foundation Post-doctoral Program (Medical Care and Social Science), 1992–2003
 Principal Investigator, “Economic Issues and Aging in Canada and the United States: Problems of Income Security,” funded by the Donner Foundation, 1989-1991
 Co-director, “Reconsidering the Institutions of Social Security,” funded by the project on the Federal Social Role Ford Foundation, 1984-1986
 Principal Investigator, “New Perspectives in Health,” funded by the Kaiser Family Foundation, 1979-1984
 Director, Research Project on National Health Insurance, funded by the Robert Wood Johnson Foundation, 1976-1978

EDITORIAL RESPONSIBILITIES:

Advisory Board, Canadian Journal, Healthcare Policy, 2006-
 Advisory Board, Canadian-American Public Policy (CAPP), 2002-
 Editorial Board, Journal of Comparative Policy Analysis, 2002-
 Editorial Advisory Board, Journal of Health Services Research and Policy, 1996-
 Editorial Board, International Journal of Health Planning and Management, 1997-
 Editorial Board, Health Policy/ Ethics/ Health Services Research, 1979-1989
 Editor, Journal of Health Politics, Policy and Law, 1980-1984; Board Member, 1984-

ADVISORY POSITIONS:

Member, Editorial Board of Pension Reforms, (on-line international information broker of research on pension issues www.PensionReforms.com), 2006–
 Member, Medicare Coverage Advisory Committee (MCAC), 2007–
 Advisory Board, On Demand Books, 2007–
 Advisory Board Chair, The Crescent Group
 Member, Advisory Board, Canadian-American Public Policy (CAPP), 2002–
 Member, Advisory Board, Yale Medical School, RWJ Clinical Scholars Program, 2000–
 Member, Advisory Board, American Ditchley Foundation, 2000-
 Member, American Board of Ophthalmology, 2000–2003
 Member, Advisory Board, Health Innovation Fund, Toronto, Ontario, Canada, 2000–
 Member, Selection Committee, “Society, Culture & the Health of Canadians,” for Social Sciences and Humanities Research Council, Ottawa, Canada, 1999
 Member, Adjudication Committee, “The Project on Trends,” of Social Sciences and Humanities Council of Canada, 1998

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Member, Board, 2030 Center: Social Security Project Advisory Board, 1998
Member, National Health Research Institute, Center for Health Economics Research, Government of Taiwan, 1997-
Member, International Advisory Board of The London School of Economics and Political Science, (Health), 1996-
Member, Committee to Visit the John F. Kennedy School of Government, 1996-2002
Member, Board of Directors, National Academy for Social Insurance, 1986-1995
Member, Advisory Board, Center for National Policy, 1986-1992
Member, Board of Directors, Center for Study of Drug Development, Tufts University, 1986-99
Senior Advisor on Health and Social Security, Mondale/Ferraro Campaign, 1983-1984
Member, President Carter's Commission on a National Agenda for the Eighties, 1980-1981
Member, Committee on Consumer Representation in Health Planning, Institute of Medicine, National Academy of Science, 1979-1980
Member, Advisory Board, Journal of Health Politics, Policy and Law, 1976-
Member, Community Action Program Commission, Madison, Wisconsin, 1968-1969
Special Assistant to Wilbur Cohen, Undersecretary of HEW, Summer 1966

CURRENT EXPERT WITNESS CASES:

Medicaid Drug Pricing Litigation (On behalf of 16 states and US Department of Justice)
Asbestos Cases (On behalf of Union Carbide, Henkel, Northrop Grumman and Dow, various Insurance Companies)
Medicare Case re: CMS ruling on durable medical equipment coverage (On behalf of plaintiff)

LITIGATION EXPERIENCE

Expert Witness, Report on Asbestos; Kelly Moore Paint Company vs. Union Carbide Corporation, for Orrick, Herrington & Sutcliffe LLP, testified in Angleton, Texas on October 18 and 19, 2004
Expert Witness, Report on Asbestos, Kanawha County, West Virginia, October 11, 2002
Expert Witness, Report on Coaches' Choice Sports Camp, Inc., et al. v. Cabrini College, et al. for Montgomery, McCracken, Walker & Rhoads, 2002-2003: testified
Expert Witness, Report on Contaminated Blood from USA, Hepatitis C, 1998 for Attorney General, Government of Canada: report supplied
Expert Witness, Report on constitutionality of the Quebec ban on private insurance for publicly financed services (The Chaoulli – Quebec case), 9/28/99 for Attorney General, Government of Canada, 1999
Expert Witness, Report on Tobacco Case, Kirkland & Ellis, Jones, Day, Reavis & Pogue, and Arnold and Porter, 1998 - 2000
Expert Witness, Report on Physician Supply and Cost Containment in New Brunswick for Attorney General, Province of New Brunswick, Canada, 2000. Testified at trial
Expert Witness and Consultant for AARP, 1995-1997: report completed on social insurance requirements for medical financing plan
Expert Witness, Report on Celotex Case - Asbestos, for Montgomery, McCracken, Walker & Rhoads, February 1996
Expert Witness for Attorney General, State of Connecticut, 1994-1995, Hospital reimbursement in Medicaid

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9/27/2002	IN RE: ASBESTOS - TRIAL GROUP CIVIL ACTION NO. 01-C-9004
4/1/2003	In RE: All Madison County Asbestos Litigation
1/23/2004	Kelly Moore Paint Co. vs. Dow Chemical Company, et al.
11/8/2005	In Re New York City Asbestos Litigation: Francis Demers

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3/29/2006 Greg and Beverly Hartell vs. Advocate Mines Limited, et al.
 6/9/2006 John McNamara and Tricia McNamara vs. Bondex International Inc, et al.
 7/3/2006 David Bakkie vs. Atlas Turner, Inc. et al.
 7/19/2006 Ruben Flores vs. Bondex International Inc., et al.
 8/22/2006 Joyce Bailey vs. Bondex International Inc., et al.
 9/15/2006 Richard George Fortini and Wanda Jane Fortini vs. 3M Company, et al.
 10/26/2006 Suzanne Marie Delisle vs. 3M Company, et al.
 11/21/2006 James Ticer vs. Amcord Inc., et al.
 11/28/2006 Henry Hall and Laura Marie Hall vs. Bondex International Inc., et al.
 3/5/2007 Andres Ginez vs. A.W.Chesterton, et al.
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 Robert Patrich; Ed Gvazdinskas vs. Union Carbide
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CONSULTANCIES:

Consultant, Astra Zeneca, 2003
 Consultant, Merck, 1996
 Consultant, Peat Marwick, 1994-1995
 Consultant to the States of Kentucky, Vermont and Delaware on Health Care Reform, 1993
 Consultant, Schering Plough, 1993
 Witness and Consultant on Medicare, Congressional Committee on Ways and Means, 1993, 1992, 1991, 1986, 1984
 Consultant to the State of Texas Health Policy Task Force, 1992
 Consultant, Select Panel for the Promotion of Child Health, Department of Health and Human Services, 1980
 Consultant to the Director, Health Staff Seminar, Washington, DC, 1974
 Consultant to National Institute for Mental Health, 1974
 Consultant to Urban Institute, Washington, DC, 1974, 1969-70
 Consultant to Rand Corporation project on National Health Insurance, 1973
 Chairman, Citizen's Advisory Health Group, Metropolitan Council, Minnesota, 1972-1973
 Consultant to Ford Foundation for evaluation of grant proposals, 1972
 Consultant to Illinois Center for Social Policy on Welfare, 1971
 Consultant to the Executive Director, President's Commission on Income Maintenance, 1968-1970
 Consultant, Office of Equal Opportunity, 1968

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